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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on cableway installations

(Text with EEA relevance)

{SWD(2014) 116 final} {SWD(2014) 117 final}

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context, reasons for and objectives of this proposal

Directive 2000/9/EC relating to cableway installations designed to carry persons ¹ was adopted on 20 March 2000 and became applicable on 3 May 2002.

Directive 2000/9/EC ensures a high level of safety for cableway installations for users, workers and third parties. It sets out essential requirements with which cableway installations, their infrastructure, subsystems and safety components must comply in order to be safe.

Directive 2000/9/EC is also an example of that Union harmonisation legislation ensuring the free movement in the EU single market, namely of subsystems and safety components for cableway installations. It harmonises the conditions for the placing on the market and putting into service of subsystems and safety components intended to be incorporated into cableway installations. Manufacturers must demonstrate that their subsystems or safety components have been designed and manufactured in compliance with the essential requirements, affix the CE marking and provide instructions for their incorporation into a cableway installation.

Directive 2000/9/EC is based on Article 114 of the Treaty on the Functioning of the European Union (hereinafter "the Treaty"). It is a total harmonisation Directive based on the "New Approach" principles, which requires manufacturers to ensure the compliance of their products with the mandatory performance and safety requirements provided for in the legislative instrument without however imposing specific technical solutions or specifications.

Directive 2000/9/EC applies to cableway installations designed to carry persons.

Traction by cable and the passenger transport function are the principal criteria determining the scope of Directive 2000/9/EC.

The main types of cableway installations covered by Directive 2000/9/EC are funiculars, gondolas, detachable chair lifts, fixed-grip chair lifts, aerial tramways, funitels, combined installations (made of several cableway types, such as those of gondolas and chairlifts) and drag lifts.

Cableway installations are defined as the whole on-site system, consisting of infrastructure, subsystems and safety components.

Cableway installations and their infrastructure are directly affected by the characteristics of the region in which they are located, by the nature and physical features of the terrain in which they are installed, by their surroundings, by atmospheric and meteorological factors as well as by structures and obstacles that may be found in their vicinity either on the ground or in the air.

In this framework, the construction and entry into service of cableway installations are subject to national authorisation procedures.

Directive 2000/9/EC sets out harmonised essential requirements with which cableway installations must comply, while Member States remain competent to regulate other aspects such as land-use, regional planning and environmental protection.

Safety components and subsystems are subject to the principle of the free movement of goods Safety components bear the CE marking indicating conformity with the requirements of the Directive 2000/9/EC, including the conformity assessment procedures.

OJEU L 106, 3.5.2000, p.21.

The proposal intends to replace Directive 2000/9/EC by a Regulation, in line with the Commission's simplification objectives.

The proposal intends to align Directive 2000/9/EC to the "goods package" adopted in 2008 and in particular to the NLF Decision EC No 768/2008.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc.). These common provisions have been reinforced to ensure that the directives can be applied and enforced more effectively in practice. New elements, such as obligations for importers, have been introduced, which are crucial for improving the safety of products on the market.

The Commission has already proposed the alignment of nine other Directives to the NLF Decision within an "alignment package" adopted on 21 November 2011. It has also proposed the alignment to the NLF Decision of Directive 97/23/EC on pressure equipment².

In view of ensuring consistency across Union harmonisation legislation for industrial products, in accordance with the political commitment resulting from the adoption of the NLF Decision and the legal obligation provided for in Article 2 of the NLF Decision, it is necessary that this proposal is in line with the provisions of the NLF Decision.

The proposal also intends to address some difficulties that have been experienced in the implementation of Directive 2000/9/EC. More particularly, authorities, notified bodies and manufacturers have had different views on whether certain types of installations come under the scope of Directive 2000/9/EC and hence have to be manufactured and certified in line with the directive's requirements and procedures. Views also differed on whether certain equipment should be considered as subsystem, infrastructure or safety component. Furthermore the Directive does not specify which type of conformity assessment procedure has to be applied to subsystems.

Those divergent approaches led to market distortions and different treatment of economic operators. Manufacturers and operators of the installations concerned had to modify the equipment or to undergo further certification which led to extra costs and to delays in the authorisation and operation of those installations.

The proposed Regulation intends therefore to enhance legal clarity about the scope of Directive 2000/9/EC and thus a better implementation of the relevant legal provisions.

Furthermore, Directive 2000/9/EC contains provisions on the conformity assessment for subsystems. However, it does not determine the concrete procedure to be followed by the manufacturer and the notified body. Furthermore, it does not offer manufacturers the range of conformity assessment procedures that are available for safety components. The proposed Regulation aligns thus the conformity assessment procedures available for subsystems with those already used for safety components, based on the conformity assessment modules set out in Decision No 768/2008/EC establishing a common framework for the marketing of products (NLF Decision). In this context, it also provides for the affixing of the CE marking to indicate compliance with its provisions, in line with the existing system for safety components.

The proposal takes into account Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation³.

COM(2013)471 final.

³ OJEU L 316, 14.11.2012.

The proposal also takes into account the proposal of the Commission of 13 February 2013 for a Regulation on market surveillance of products⁴, which intends to set out a single legal instrument on market surveillance activities in the field of non-food goods, consumer or nonconsumer products and products covered or not by Union harmonisation legislation. This proposal merges the rules on market surveillance of Directive 2001/95/EC on general product safety⁵, Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products⁶ and of sector-specific harmonisation legislation in order to increase the effectiveness of market surveillance activities within the Union. The proposed Regulation on market surveillance of products contains also the relevant provisions on market surveillance and safeguard clauses. Therefore, provisions in existing sector specific harmonisation legislation that relate to market surveillance and safeguard clauses should be removed from that harmonisation legislation. The overacting objective of the proposed Regulation on market surveillance of products is to simplify the Union market surveillance framework fundamentally so that it works better for its main users: market surveillance authorities and economic operators. Directive 2000/9/EC provides for a safeguard clause procedure for subsystems and safety components. In line with the framework intended to be established by the proposed Regulation on the market surveillance of products, this proposal does not include the provisions on market surveillance and safeguard clause procedures for subsystems and safety components provided for in the NLF Decision. However, in order to ensure legal clarity, it makes a reference to the proposed Regulation on market surveillance of products.

Consistency with other policies and objectives of the Union

This initiative is in line with the Single Market Act⁷, which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

2. CONSULTATION OF THE INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of the interested parties

The revision of Directive 2000/9/EC has been lengthy and extensively discussed since 2010. More particularly, it has been discussed within the Member States Working Group on Cableway Installations, with national experts responsible for the implementation of the Directive, within the Standing Committee provided for by Directive 2000/9/EC, the Administrative Cooperation Group for Market Surveillance of Cableway Installations (AdCo) and the Cableway Installations Sectoral Group (CSG) of the European Co-ordination of Notified Bodies, as well as with industry and user associations.

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Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council. COM(2013) 75 final.

OJ L11, 15.1.2002, p.4.

⁶ OJ L218, 13.8.2008, p.30.

Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.

Member States and stakeholders, including manufacturers' organisations, notified bodies and representatives of standardisation bodies, have been involved in the Impact Assessment process from the beginning. In the framework of the Standing Committee provided for by Directive 2000/9/EC, regular discussions took place about the functioning of the Directive and the potential issues that would require improvements, either through legislative or non-legislative means.

Additionally, three specific consultations have been carried out.

The first consultation took place in the first half of 2010 in the framework of the preparation of the Report on the implementation of Directive 2000/9/EC provided for by its Article 21(4).

In its First Report on the implementation of Directive 2000/9/EC⁸, the Commission noted that the Directive has been successful in establishing an internal market for subsystems and safety components, while guaranteeing a uniform and high level of safety. It also identified some issues to be examined.

The issues to be examined were the following:

- The extent of the scope of Directive 2000/9/EC, in particular with regard to new types of cableway installations;
- The lack of an appropriate range of conformity assessment procedures for subsystems, which has led to divergent interpretations and implementation of the conformity assessment of subsystems;
- The need to align Directive 2000/9/EC to the NLF Decision.

The second and the third consultation took place in 2012 as part of the Impact Assessment Study the first one concerned the existing situation and the other one the policy options. The Final Report of the Impact Assessment study has been formally presented and discussed at the Standing Committee meetings held on 25 September 2012 and 8 April 2013, in which Member States and sectoral stakeholders had the opportunity to express a number of opinions, contributions and position papers on the policy options included in the study.

Stakeholders have actively contributed to identify the issues needing solutions to improve the functioning of Directive 2000/9/EC. The majority of stakeholders agree with the problems identified. An important number of respondents to the consultation carried out in the context of the Impact Assessment Study have experienced problems with the definition of Cableway installations and the borderline with the scope of the Directive 95/16/EC relating to lifts⁹.

In view of the amount of information collected and the rather technical issues, no open public consultation was launched, as targeted expertise consultations were deemed more appropriate for this quite technical initiative.

Collection and use of expertise - Impact assessment

An impact assessment on the revision of Directive 2000/9/EC has been conducted.

Based on the information collected, the impact assessment carried out by the Commission examined and compared three options:

Option 1 – "Do nothing" - No changes to the existing situation

This option proposes no changes to Directive 2000/9/EC.

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Report from the Commission to the European Parliament and the Council, COM(2011) 123 final, 16.3.2011.

⁹ OJ L213, 7.9.1995, p.1.

Option 2 –Intervention by non-legislative measures

Option 2 considers the possibility of providing more extensive guidance on the implementation of Directive 2000/9/EC with regard to its scope and of recommending the application of specific conformity assessment procedures for the assessment of subsystems, mainly via a redrafting of the Application Guide to Directive 2000/9/EC.

Option 3 – Intervention by legislative measures

This option consists in modifying Directive 2000/9/EC.

Combination of options 2 and 3 were found to be the preferred solution because:

- it is considered the most to address the problem as it will provide clarification in the scope definitions and consistency and flexibility of conformity assessment procedures for subsystems and safety components;
- it does not entail significant costs for economic operators and notified bodies; for those who are already acting responsibly, no significant economic or social impacts could be identified;
- it will improve the functioning of the internal market of subsystems and safety components by ensuring equal treatment of all economic operators, notably importers and distributors, as well as notified bodies;
- option 1 does not provide answers to the problem of legal uncertainty due to some provisions of Directive 2000/9/EC and therefore will not lead to its better implementation.

The proposal includes:

- The clarification of the scope with regard to cableway installations designed for both transport and leisure purposes;
- The introduction of a range of conformity assessment procedures for subsystems based on the existing conformity assessment modules for safety components as aligned to the NLF Decision;
- The alignment to the NLF Decision.

The impact of the proposal will guarantee a fair level playing field for the economic operators and will enhance protection of the safety of passengers and other users, workers and third parties.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Scope and definitions

The scope of the proposed Regulation corresponds to the scope of Directive 2000/9/EC, and covers cableway installations, including their infrastructure, as well as subsystems and safety components for cableway installations.

The proposal clarifies and updates the existing scope.

In particular, in light of the development of new types of cableway installations, it is clarified that the exclusion of cableway installations used for leisure purposes in fairgrounds or amusement parks does not apply to cableway installations that are intended for a dual function, namely of transporting persons and for leisure activities.

The proposal maintains the exclusion of certain cableway installations intended for agricultural or industrial purposes, but it clarifies that it also covers cableway installations intended for the service of mountain shelters or huts that are not intended for the transport of the public.

The current exclusion of cable-operated ferries is also updated to all cable-operated installations where the users or carriers are water-borne, such as cable-operated water ski installations.

The exclusions provided for in Directive 2000/9/EC relating to rack-and-pinion railways and chain-driven installations are not reintroduced since these installations do not correspond to the definition of cableway installations.

The general definitions resulting from the alignment to the NLF Decision have been inserted.

3.2. Obligations of economic operators

The proposal contains, with regard to subsystems and safety components, the typical provisions for product-related Union harmonisation legislation and sets out the obligations of the relevant economic operators (manufacturers, authorised representatives, importers and distributors), in accordance with the NLF Decision.

3.3. Harmonised standards

Compliance with harmonised standards provides for a presumption of conformity with the essential requirements. Regulation (EU) No 1025/2012 sets out a horizontal legal framework for European standardisation. The Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisation, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently the provisions of Directive 2000/9/EC which cover the same aspects have not been reintroduced in this proposal for reasons of legal certainty.

3.4. Conformity assessment

The proposal keeps the conformity assessment procedures for safety components provided for under Directive 2000/9/EC. It however updates the corresponding modules in line with the NLF Decision.

In particular, it keeps the requirement for a notified body intervention in the design and production phase of all subsystems and safety components.

The proposal introduces a range of conformity assessment procedures for subsystems based on the conformity assessment modules of the NLF Decision. In this framework, it also introduces the CE marking for subsystems, as there is no reason to treat them differently than the safety components, for which Directive 2000/9/EC provides already the affixing of the CE marking to indicate their conformity with its requirements.

3.5. Notified bodies

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and for the confidence of all interested parties in the New Approach system.

Therefore, in line with the NLF Decision, the proposal reinforces the notification criteria for notified bodies and introduces specific requirements for notifying authorities.

3.6. Implementing acts

The proposal empowers the Commission to adopt, where appropriate, implementing acts to ensure the uniform application of this Regulation in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

Those implementing acts will be adopted in accordance with the provisions on implementing acts laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers.

3.7. Final provisions

The proposed Regulation will become applicable two years after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements.

However, the designation of notified bodies pursuant to the new requirements and process needs to start shortly after the entry into force of this Regulation. This will ensure that by the date of application of the proposed Regulation, sufficient notified bodies will have been designated in accordance with the new rules so as to avoid problems with production continuity and market supply.

A transitional provision is foreseen for the certificates issued by notified bodies under Directive 2000/9/EC with regard to subsystems and safety components so as to allow stocks to be absorbed and ensure a smooth transition to the new requirements.

A transitional provision is foreseen for the entry into service of cableway installations constructed under Directive 2000/9/EC so as to ensure a smooth transition to the new requirements.

Directive 2000/9/EC will be repealed and replaced by the proposed Regulation.

3.8. Union competence, legal basis, subsidiarity principle and legal form

Legal basis

The proposal is based on Article 114 of the Treaty.

Subsidiarity principle

The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 2000/9/EC, namely, the economic operators' obligations, the traceability provisions, the provisions on the assessment and notification of conformity assessment bodies.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the Union, which undermines the objective of Directive 2000/9/EC. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. Coordinated action at Union level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at Union level.

Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

The new or modified obligations do not impose unnecessary burdens and costs on industry - especially on small and medium sized enterprises - or administrations. Where modifications have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of

modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

Legislative technique used

The proposal takes the form of a Regulation.

The proposed change from a Directive to a Regulation takes into account the Commission's general objective to simplify the regulatory environment and the need to ensure a uniform implementation throughout the Union of the proposed legislation.

The proposed Regulation is based on Article 114 of the Treaty and aims to ensure the proper functioning of the internal market for subsystems and safety components intended to be incorporated into cableway installations, while maintaining the existing role for Member States with respect to cableway installations. It imposes clear and detailed rules which will become applicable in a uniform manner at the same time throughout the Union.

In accordance with the total harmonisation principles, Member States are not allowed to impose more stringent or additional requirements in their national legislation for the placing on the market of subsystems and safety components. In particular, the mandatory essential requirements and the conformity assessment procedures to be followed by manufacturers must be identical in all Member States.

The same applies with regard to the provisions that have been introduced as a result from the alignment to the NLF Decision. Those provisions are clear and sufficiently precise to be applied directly by the actors concerned.

The obligations provided for the Member States, such as the obligation to assess, appoint and notify the conformity assessment bodies are, in any case, not transposed as such into national law but implemented by the Member States by means of the necessary regulatory and administrative arrangements. This will not change when the obligations concerned are set out in a Regulation.

Therefore, Member States have almost no flexibility in transposing a Directive into their national law. The choice of a Regulation will however allow them to save the costs associated with the transposition of a Directive.

Additionally, a Regulation avoids the risk of possible diverging transpositions of a Directive by the different Member States, which might lead to different levels of safety protection and create obstacles to the internal market, undermining thus its effective implementation.

The change from a Directive to a Regulation will not lead to any change in the regulatory approach.

The characteristics of the New Approach will be fully preserved, in particular the flexibility given to manufacturers in the choice of the means employed to comply with the essential requirements and in the choice of the procedure used, amongst the available conformity assessment procedures, to demonstrate compliance of subsystems and safety components. The existing mechanisms supporting the implementation of the legislation (standardisation process, working groups, administrative cooperation, the development of guidance documents etc.) will not be affected by the nature of the legal instrument.

Furthermore, the choice of a Regulation does not mean that the decision-making process is centralised. Member States retain their competence with regard to cableway installations and the implementation of the harmonised provisions, e.g. the designation and accreditation of notified bodies, the conduct of market surveillance and enforcement action (e.g. penalties).

Finally, the use of Regulations in the area of internal market legislation, allows, in accordance also with the preference expressed by stakeholders, to avoid the risk of 'gold plating'. It also allows manufacturers to work directly with the Regulation text instead of needing to identify and examine 28 transposition laws.

On this basis, it is considered that the choice of a Regulation is the most appropriate and less costly solution for all involved parties as it will allow a more rapid and coherent application of the proposed legislation and will establish a clearer regulatory environment for economic operators, while avoiding transposition costs to Member States.

4. BUDGETARY IMPLICATION

This proposal does not have any implications for the EU budget.

5. ADDITIONAL INFORMATION

Repeal of existing legislation

The adoption of the proposal will lead to repeal of Directive 2000/9/EC.

European Economic Area

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on cableway installations

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee¹⁰,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2000/9/EC of the European Parliament and of the Council¹¹ on cableway installations lays down rules for cableway installations that are designed, constructed and operated in view of transporting persons.

(2) Directive 2000/9/EC is based on the New Approach principles, as set out in Council Resolution of 5 May 1985 on a new approach to technical harmonisation and standards¹². Thus, it sets out only the essential requirements applying to cableway installations, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council¹³ on European Standardisation. Conformity with the harmonised standards so set, the reference number of which is published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 2000/9/EC. Experience has shown that those basic principles have worked well in this sector and should be maintained and even further promoted.

14.11.2012, p.12).

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OJ C [...], [...], p. [...].

Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons (OJ L 106, 3.5.2000, p.21).

OJ C 136, 4.6.1985, p.1.

Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316,

- (3) Experience from the implementation of Directive 2000/9/EC showed the need to modify some of its provisions in order to clarify and update them and ensure thus legal certainty mainly as regards the scope and the conformity assessment of subsystems.
- (4) Decision No 768/2008/EC of the European Parliament and of the Council¹⁴ on a common framework for the marketing of products lays down a common framework of general principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 2000/9/EC should therefore be adapted to that Decision.
- (5) As a number of changes are to be made to Directive 2000/9/EC, it should be repealed and replaced in the interests of clarity. Since the scope, essential requirements and conformity assessment procedures must be identical in all Member States, there is almost no flexibility in transposing a Directive based on the New Approach principles into national law. In order to simplify the regulatory framework, Directive 2000/9/EC should be replaced by a Regulation, which is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States and ensures thus a uniform implementation throughout the Union.
- (6) Regulation (EC) No 765/2008 of the European Parliament and of the Council¹⁵ setting out the requirements for accreditation and market surveillance relating to the marketing of products lays down horizontal provisions on the accreditation of conformity assessment bodies [,on market surveillance of products and controls on products from third countries] and on the CE marking.
- (7) Regulation (EU) No [.../...] [on market surveillance of products]¹⁶ provides detailed rules on market surveillance and on controls of products entering the Union from third countries, including subsystems and safety components. It also sets out a safeguard clause procedure. Member States are to organise and carry out market surveillance, appoint market surveillance authorities and specify their powers and duties. They are also to set up general and sector-specific market surveillance programs.
- (8) The scope of Directive 2000/9/EC should be maintained. This Regulation should apply to cableway installations designed to transport persons used in high-altitude tourist resorts or in urban transport facilities. Cableway installations are mainly lift systems, such as funicular railways, aerial ropeways, cable cars, gondolas, chairlifts and drag lifts. Traction by cable and the passenger transport function are the essential criteria determining the cableway installations covered by this Regulation.
- (9) New types of cableway installations have been developed that are intended for both transport and leisure activities. Such installations should be covered by this Regulation.
- (10) It is appropriate to exclude certain cableway installations from the scope of this Regulation, either because they are subject to other specific Union harmonisation legislation or because they can be adequately regulated at national level.

OJ L [.....].

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Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p.82).

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p.30).

- (11) Cable-operated lifts, whether vertical or inclined, permanently serving specific levels of buildings and constructions other than the stations, are subject to specific Union legislation and should be excluded from the scope of this Regulation.
- (12) In order to ensure legal certainty, the exclusion of the cable-operated ferries should cover all cable-operated installations where the users or carriers are water-borne, such as cable-operated water ski installations.
- (13) In order to ensure that cableway installations and their infrastructure, subsystems and safety components guarantee a high level protection of the health and safety of persons it is necessary to lay down rules for the design and the construction of cableway installations.
- (14) Member States should ensure the safety of cableway installations at the time of their construction, entry into service and during their operation.
- (15) This Regulation does not affect the right of the Member States to specify the requirements they deem necessary as regards land-use, regional planning and in order to ensure the protection of the environment and of the health and safety of persons and in particular workers when using cableway installations.
- (16) This Regulation does not affect the right of the Member States to specify adequate procedures for the authorisation of planned cableway installations, the inspection of cableway installations prior to their entry into service and their monitoring during operation.
- (17) This Regulation should take into account the fact that the safety of cableway installations depends equally on the surrounding conditions, on the quality of the industrial goods supplied and on the way in which they are assembled, installed on site and monitored during operation. The causes of serious accidents may be linked to the choice of site, to the system of transport itself, to the structures, or to the way in which the system is operated and maintained.
- (18) Although this Regulation is not to cover the actual operation of cableway installations, it should provide a general framework intended to ensure that such installations situated on the territory of Member States, are operated in such a way as to offer users, operating personnel and third parties a high degree of protection.
- (19) In the case of cableway installations, technological innovations can be verified and submitted to full-scale tests only on the occasion of the construction of a new cableway installation. In these circumstances, a procedure should be provided which, while ensuring that the essential requirements are complied with, also enables to take into account the particular conditions of a specific cableway installation.
- (20) Member States should take the necessary steps to ensure that cableway installations enter into service only if they comply with this Regulation and they are not liable to endanger the health and safety of persons or property when properly installed, maintained and operated in accordance with their intended purpose.
- (21) Member States should lay down procedures for authorising the construction of planned cableway installations and the modification of such installations and for their entry into service in order to ensure that the cableway installation is safely constructed and assembled on site, in accordance with the safety analysis and the safety report and all relevant regulatory requirements.
- (22) The safety analysis for planned cableway installations should identify the components on which the safety of the cableway installation depends.

- (23) The safety analysis for planned cableway installations should take into account the constraints linked to the operation of cableway installations, albeit not in such a way as to jeopardise the principle of free movement of goods for subsystems and safety components or the safety of the cableway installations themselves.
- (24) This Regulation should aim to ensure the functioning of the internal market of subsystems of cableway installations and of safety components for cableway installations. Subsystems and safety components complying with the provisions of this Regulation should benefit from the principle of free movement of goods.
- (25) Subsystems and safety components should be allowed to be incorporated in a cableway installation provided that they permit the construction of cableway installations which comply with this Regulation and are not liable to endanger the health and safety of persons or property when properly installed, maintained and operated in accordance with their intended purpose.
- (26) The essential requirements should be interpreted and applied so as to take account of the state of the art at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection.
- (27) Economic operators should be responsible for the compliance of subsystems and safety components with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as the health and safety of users and other persons and protection of property and to guarantee fair competition on the Union market.
- (28) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market subsystems and safety components which are in conformity with this Regulation. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (29) The manufacturer of subsystems and safety components, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer of the subsystem or the safety component.
- (30) In order to facilitate the communication between economic operators and national market surveillance authorities, Member States should encourage economic operators to include a website address in addition to the postal address.
- (31) It is necessary to ensure that subsystems and safety components from third countries entering the Union market comply with the requirements of this Regulation, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those subsystems and safety components. Provision should therefore be made for importers to make sure that the subsystem or safety component they place on the market comply with the requirements of this Regulation and that they do not place on the market subsystems and safety components which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that subsystem and safety component marking and documentation drawn up by manufacturers are available for inspection by the competent supervisory authorities.
- (32) The distributor makes a subsystem or a safety component available on the market after it has been placed on the market by the manufacturer or the importer and should act

- with due care to ensure that its handling of the subsystem or the safety component does not adversely affect its compliance.
- (33) When placing on the market a subsystem or a safety component, every importer should indicate on the subsystem or safety component his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the safety component does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the safety component.
- (34) Any economic operator that either places a subsystem or a safety component on the market under his own name or trademark or modifies a subsystem or a safety component in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (35) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the subsystems or the safety components concerned.
- (36) Ensuring traceability of a subsystem or safety component throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant subsystems or safety components available on the market.
- (37) This Regulation should be limited to the expression of the essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for cableway installations which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, construction and operation of cableway installations.
- (38) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.
- (39) In order to enable economic operators to demonstrate and the competent authorities to ensure that subsystems and safety components made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (40) Manufacturers of subsystems or safety components should draw up an EU declaration of conformity to provide information required under this Regulation on the conformity of subsystem or safety component with the requirements of this Regulation and of other relevant Union harmonisation legislation. The EU declaration of conformity should accompany the subsystem or safety component.

- (41) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for a subsystem or a safety component should be available in a single EU declaration of conformity.
- (42) The CE marking, indicating the conformity of a subsystem or a safety component is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship with other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Regulation.
- (43) A check of compliance of subsystems and safety components with the essential requirements provided for in this Regulation is necessary in order to provide effective protection for users and third parties.
- (44) In order to ensure compliance of subsystems and safety components with the essential requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Those procedures should be set on the basis of the conformity assessment modules laid down in Decision No 768/2008/EC.
- (45) The conformity assessment procedures set out in this Regulation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (46) Experience has shown that the criteria set out in Directive 2000/9/EC that conformity assessment bodies have to fulfil in order to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of these bodies throughout the Union. It is, however, essential that all conformity assessment bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (47) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (48) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (49) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (50) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

- Conformity assessment bodies frequently subcontract parts of their activities linked to (51)the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the subsystems and safety components to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (52)It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (53)Since conformity assessment bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- In the interests of competitiveness, it is crucial that conformity assessment bodies (54)apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between conformity assessment bodies.
- In order to ensure uniform conditions for the implementation of this Regulation, (55)implementing powers should be conferred to the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁷.
- (56)The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (57)It is necessary to provide for transitional arrangements that allow the making available on the market and the putting into service of subsystems and safety components that have already been placed on the market in accordance with Directive 2000/9/EC.
- (58)It is necessary to provide for transitional arrangements that allow the entry into service of cableway installations that have already been constructed in accordance with Directive 2000/9/EC.
- (59)Member States should lay down rules on penalties applicable to infringements to this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.
- (60)Since the objective of this Regulation, namely to ensure that cableway installations fulfil the requirements providing for a high level protection of and safety of users while guaranteeing the functioning of the internal market for subsystems and safety components cannot be sufficiently achieved by the Member States and can therefore,

¹⁷ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. 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

Subject matter

This Regulation lays down rules on the design and construction of cableway installations designed to transport persons and on the making available on the market and the free movement of subsystems and safety components for such installations.

Article 2

Scope

- (1) This Regulation shall apply to cableway installations designed to transport persons and to subsystems and safety components for such installations.
- (2) This Regulation shall not apply to the following:
 - (a) lifts within the meaning of Directive 95/16/EC of the European Parliament and of the Council¹⁸ on lifts;
 - (b) cable-operated tramways of traditional construction;
 - (c) installations intended for agricultural purposes and for the service of mountain shelters and huts that are not intended for the transport of the public;
 - (d) on-site or mobile equipment for use in fairgrounds and/or amusement parks which are exclusively designed for leisure purposes and not as a means for transporting persons;
 - (e) mining installations or other industrial on site installations used for industrial activities;
 - (f) installations in which the users or their carriers are water-borne.

Article 3

Definitions

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

"cableway installation" means the whole on site system, consisting of infrastructure and subsystems intended for installations made up of several components, designed, constructed, assembled and put into service with the object of transporting persons, where the traction is provided by cables positioned along the line of travel;

Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p.1).

- (2) "subsystem" means the systems listed in Annex I as such or a combination thereof;
- (3) "infrastructure" means the layout, system data, station structures and structures along the line especially designed for each installation and constructed on site and which are needed for the construction and the operation of the installation, including the foundations:
- (4) "safety component" means any basic component, set of components, subassembly or complete assembly of equipment and any device intended to be incorporated in a subsystem or a cableway installation for the purpose of ensuring a safety function, the failure of which endangers the safety or health of persons, users, operating personnel or third parties;
- (5) "operability" means all the technical provisions and measures which have an impact on design and construction and are necessary in order for the cableway installation to operate safely;
- (6) "maintainability" means all the technical provisions and measures which have an impact on design and construction and are necessary for maintenance, designed to ensure that the cableway installation operates safely;
- (7) "cable car" means a cableway installation where the carriers are suspended from one or more cables;
- (8) "drag lift" means a cableway installation where users with appropriate equipment are towed along a prepared track;
- (9) "funicular railway" means a cableway installation in which the carriers are hauled along rails that are on the ground or supported by fixed structures;
- (10) "making available on the market" means any supply of a subsystem or a safety component for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- "placing on the market" means the first making available of a subsystem or a safety component on the Union market;
- (12) "entry into service" means the initial operation of a cableway installation;
- "manufacturer" means any natural or legal person who manufactures a subsystem or a safety component or who has such a subsystem or a safety component designed or manufactured, and markets that subsystem or safety component under his name or trademark;
- "authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- "importer" means any natural or legal person established within the Union who places a subsystem or a safety component from a third country on the Union market;
- "distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a subsystem or a safety component available on the market:
- "economic operators" means the manufacturer, the authorised representative, the importer and the distributor of a subsystem or a safety component;
- "technical specification" means a document that prescribes technical requirements to be fulfilled by an installation, infrastructure, subsystem or safety component;

- "harmonised standard" means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;
- (20) "accreditation" means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;
- "national accreditation body" means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;
- "conformity assessment" means the process demonstrating whether the essential requirements of this Regulation relating to a subsystem or safety component have been fulfilled;
- "conformity assessment body" means a body that performs conformity assessment activities relating to a subsystem or safety component, including calibration, testing, certification and inspection;
- "recall" means any measure aimed at achieving the return of a subsystem or a safety component that has already been incorporated into a cableway installation;
- "withdrawal" means any measure aimed at preventing a subsystem or a safety component in the supply chain from being made available on the market;
- (26) "CE marking" means a marking by which the manufacturer indicates that the subsystem or the safety component is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- "Union harmonisation legislation" means any Union legislation harmonising the conditions for the marketing of products.

Article 4

Making available on the market of subsystems and safety components

- (1) Member States shall take all appropriate measures to ensure that subsystems and safety components are made available on the market only if they satisfy the requirements of this Regulation.
- (2) Member States shall take all appropriate measures, in accordance with Article 9, to determine the procedures to ensure that the subsystems and safety components are incorporated into cableway installations only if they enable the construction of cableway installations which satisfy the requirements of this Regulation and are not liable to endanger the health and safety of persons or property when properly incorporated, maintained and operated in accordance with their intended purpose.

Article 5

Entry into service of cableway installations

- (1) Member States shall take all appropriate measures in accordance with Article 9, to determine the procedures to ensure that cableway installations enter into service only if they satisfy the requirements of this Regulation and they are not liable to endanger the health and safety of persons or property when properly installed, maintained and operated in accordance with their intended purpose.
- (2) Cableway installations which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the*

- European Union shall be presumed to be in conformity with the essential requirements covered by those standards or parts thereof, referred to in Annex II.
- (3) This Regulation shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using the cableway installations in question, provided that this does not mean that the cableway installations are modified in a way not specified in this Regulation.

Article 6

Essential requirements

The cableway installations and their infrastructure, subsystems and safety components shall satisfy the essential requirements applicable to them set out in Annex II.

Article 7

Free movement of subsystems and safety components

Member States shall not prohibit, restrict or impede the making available on the market of subsystems and safety components which comply with this Regulation.

Article 8

Safety analysis and safety report for planned cableway installations

- (1) All planned installations shall be subject to a safety analysis as defined in Annex III which shall cover all safety aspects of the cableway installation and its environment in the context of the design, construction and entry into service and shall make it possible to identify from past experience risks liable to occur during the operation of the cableway installation.
- (2) The safety analysis shall be included in a safety report. That report shall recommend the measures envisaged to deal with such risks and include a list of the subsystems and safety components to be incorporated into the cableway installation.

Article 9

Authorisation of cableway installations

- (1) Member States shall lay down procedures for authorising the construction and the entry into service of cableway installations which are located within its territory.
- (2) Member States shall ensure that the safety analysis, the safety report, the EU declaration of conformity and the other documents relating to the conformity of subsystems and safety components as well as the documentation concerning the characteristics of the cableway installation are submitted to the authority responsible for approving the cableway installation. The documentation concerning the cableway installation shall also include the necessary conditions, including the restrictions on operation, and full details for servicing supervision, adjustment and maintenance of the cableway installation. A copy of those documents shall be kept at the cableway installation.
- (3) In the event that important characteristics, subsystems or safety components of existing cableway installations undergo modifications for which a new authorisation

- for entry into service is required by the Member State concerned, such modifications and their repercussions on the cableway installation as a whole shall satisfy the essential requirements set out in Annex II.
- (4) Member States shall not use the provisions referred to in paragraph 1 to prohibit, restrict or hinder, on grounds related to the aspects covered by this Regulation, the construction and the entry into service of cableway installations which comply with this Regulation and do not present a risk to the health and safety of persons or to property when properly installed in accordance with their intended purpose.
- (5) Member States shall not use the provisions referred to in paragraph 1 to prohibit, restrict or hinder the free movement of subsystems and safety components which comply with this Regulation.

Article 10

Operation of cableway installations

- (1) Member States shall ensure that a cableway installation remains in operation only if it complies with the conditions set out in the safety report.
- (2) If a Member State finds that an approved cableway installation which is used in accordance with its intended purpose is liable to endanger the health and safety of persons and, where appropriate, property, it shall take all appropriate measures to restrict the conditions of operation of the cableway installation or to prohibit the operation thereof.

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS OF SUBSYSTEMS AND SAFETY COMPONENTS

Article 11 [Article R2 of Decision No 768/2008/EC]

Obligations of manufacturers

- (1) When placing their subsystems or safety components on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex II.
- (2) Manufacturers of subsystems or safety components shall draw up the technical documentation set out in Annex V and carry out the relevant conformity assessment procedure referred to in Article 18 or have it carried out.
 - Where compliance of a subsystem or a safety component with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.
- (3) Manufacturers shall keep the technical documentation and the EU declaration of conformity for 30 years after the subsystem or the safety component has been placed on the market.
- (4) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in

other technical specifications by reference to which the conformity of the subsystem or the safety component is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a subsystem or a safety component, manufacturers shall, to protect the health and safety of users, carry out sample testing of the subsystem or the safety component made available on the market, investigate, and, if necessary, keep a register of complaints of non-conforming subsystems or safety components and recalls of such subsystems or safety components, and shall keep distributors informed of any such monitoring.

- (5) Manufacturers shall ensure that their subsystems or safety components are accompanied by the EU declaration of conformity and that they bear a type, batch or serial number or other element allowing their identification.
 - Where the size or nature of the safety component does not allow it, manufacturers shall ensure that the required information is provided on the packaging or in the instructions accompanying the safety component.
- (6) Manufacturers shall indicate on the subsystem or the safety component their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on the packaging and in the instructions accompanying the safety component. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and the market surveillance authorities as determined by the Member State concerned.
- (7) Manufacturers shall ensure that the subsystem or the safety component is accompanied by the EU Declaration of conformity and by instructions and safety information, in a language which can be easily understood by users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible.
- (8) Manufacturers who consider or have reason to believe that the a subsystem or a safety component which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective measures necessary to bring that subsystem or safety component into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the subsystem or the safety component presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the subsystem or the safety component available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
- (9) Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component with this Regulation, in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the subsystems or safety components which they have placed on the market.

Authorised representatives

- (1) A manufacturer may, by a written mandate, appoint an authorised representative.
 - The obligations laid down in Article 11(1) and the obligation to draw up of technical documentation shall not form part of the authorised representative's mandate.
- (2) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - (a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 30 years after the subsystem or the safety component has been placed on the market;
 - (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component;
 - (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by subsystems or safety components covered by the authorised representative's mandate.

Article 13 [Article R4 of Decision No 768/2008/EC]

Obligations of importers

- (1) Importers shall place only compliant subsystems or safety components on the market.
- (2) Before placing on the market a subsystem or a safety component, importers shall ensure that the appropriate conformity assessment procedure in accordance with Article 18 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the subsystem or the safety component is accompanied by the EU declaration of conformity, that it bears the CE marking and is accompanied by instructions and safety information and that the manufacturer has complied with the requirements set out in Article 11(5) and (6) respectively.

Where an importer considers or has reason to believe that a subsystem or a safety component is not in conformity with the essential requirements set out in Annex II, he shall not place the subsystem or the safety component on the market until it has been brought into conformity. Furthermore, where the subsystem or the safety component presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

(3) Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the subsystem or the safety component or where that is not possible, on its packaging and in the instructions accompanying the safety component. The contact details shall be in a language easily understood by users and market surveillance authorities as determined by the Member State concerned.

- (4) Importers shall ensure that the subsystem or the safety component is accompanied by instructions and safety information, in a language which can be easily understood by users, as determined by the Member State concerned.
- (5) Importers shall ensure that, while a subsystem or a safety component is under their responsibility, storage or transport conditions do not jeopardise their compliance with the requirements set out in Annex II.
- When deemed appropriate with regard to the risks presented by a subsystem or a safety component, importers shall, to protect the health and safety of the users, upon a duly justified request of the competent authorities, carry out sample testing of subsystems or safety components made available on the market, investigate, and, if necessary, keep a register of complaints of nonconforming subsystems or safety components and recalls of such subsystems or safety components, and shall keep distributors informed of any such monitoring.
- (7) Importers who consider or have reason to believe that a subsystem or a safety component which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that subsystem or safety component into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the subsystem or the safety component presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the subsystem or the safety component available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
- (8) Importers shall, for 30 years after the subsystem or the safety component has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
- (9) Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.

Article 14 [Article R5 of Decision No 768/2008/EC]

Obligations of distributors

- (1) When making a subsystem or a safety component available on the market distributors shall act with due care in relation to the requirements of this Regulation.
- (2) Before making a subsystem or a safety component available on the market distributors shall verify that the subsystem or the safety component bears the CE marking and it is accompanied by the EU declaration of conformity and by instructions and safety information in a language which can be easily understood by users as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 11(5) and (6) and Article 13(3).

Where a distributor considers or has reason to believe that a subsystem or a safety component is not in conformity with the essential requirements set out in Annex II, he shall not make the subsystem or the safety component available on the market until it has been brought into conformity. Furthermore, where the subsystem or the safety component presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

- (3) Distributors shall ensure that, while a subsystem or a safety component is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex II.
- (4) Distributors who consider or have reason to believe that a subsystem or a safety component which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that subsystem or safety component into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the subsystem or the safety component presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the subsystem or the safety component available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
- (5) Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the subsystem or the safety component which they have made available on the market.

Article 15 [Article R6 of Decision No 768/2008/EC]

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer under Article 11, where he places a subsystem or a safety component on the market under his name or trademark or modifies a subsystem or a safety component already placed on the market in such a way that compliance with the requirements of this Regulation may be affected.

Article 16 [Article R7 of Decision No 768/2008/EC]

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a subsystem or a safety component;
- (b) any economic operator to whom they have supplied a subsystem or a safety component.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 30 years after they have been supplied with the subsystem or the safety

component and for a period of 30 years after they have supplied the subsystem or the safety component.

CHAPTER III

CONFORMITY OF SUBSYSTEMS AND SAFETY COMPONENTS

Article 17 [Article R8 of Decision No 768/2008/EC]

Presumption of conformity

Subsystems and safety components which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements covered by those standards or parts thereof, set out in Annex II.

Article 18

Conformity assessment

- (1) Before a subsystem or a safety component is placed on the market, the manufacturer shall submit the subsystem or the safety component to a conformity assessment procedure in accordance with paragraph 2.
- (2) The means of certification of conformity of subsystems and safety components shall be, at the choice of the manufacturer, any of the following conformity assessment procedures:
 - (a) EU-type examination (Module B production type) set out in Annex IV combined with either of the following:
 - (i) conformity to type based on quality assurance of the production process (Module D), set out in Annex V:
 - (ii) conformity to type based on subsystem or safety component verification (Module F), set out in Annex VI.
 - (b) conformity based on unit verification (Module G), set out in Annex VII.
 - (c) conformity based on full quality assurance (Module H), set out in Annex VIII.
- (3) After completion of the procedures referred to in paragraph 2, the manufacturer shall, in accordance with Article 21, affix the CE marking on the subsystem or the safety component that complies with this Regulation.
- (4) Paragraphs 1, 2 and 3 shall also apply with regard to subsystems and safety components intended for the manufacturer's own purposes.
- (5) Records and correspondence relating to conformity assessment shall be drawn up in the official language(s) of the Member State where the body carrying out the procedures referred to in paragraph 2 is established or in a language accepted by that body.

Article 19

EU declaration of conformity

- (1) The EU declaration of conformity for a subsystem or a safety component shall state that the fulfilment of essential requirements set out in Annex II has been demonstrated.
- The EU declaration of conformity shall have the model structure set out in Annex X and shall contain the elements specified in the relevant conformity assessment procedures set out in Annexes IV to VIII and shall be continuously updated. It shall accompany the subsystem or the safety component and shall be translated into the language or languages required by the Member State in whose market the subsystem or the safety component is placed or made available on the market.
- (3) Where a subsystem or a safety component is subject to more than one Union acts requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.
- (4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the subsystem or the safety component with the requirements laid down in this Regulation.

Article 20 [Article R11 of Decision No 768/2008/EC]

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 21 [Article R12 of Decision No 768/2008/EC]

Rules and conditions for the affixing of the CE marking

- (1) The CE marking shall be affixed visibly, legibly and indelibly to the subsystem or the safety component or to their data plate.
- (2) The CE marking shall be affixed before the subsystem or the safety component is placed on the market.
- (3) The CE marking shall be followed by the identification number of the notified body involved in the production control phase.
- (4) The CE marking and the identification number referred to in paragraph 3 may be followed by any other mark indicating a special risk or use.

CHAPTER IV

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 22 [Article R13 of Decision No 768/2008/EC]

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks in accordance with Article 18.

Article 23 [Article R14 of Decision No 768/2008/EC]

Notifying authorities

- (1) Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.
- (2) Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
- (3) Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 26(1) to (6). In addition it shall have arrangements to cover liabilities arising out of its activities.
- (4) The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 24 [Article R15 of Decision No 768/2008/EC]

Requirements relating to notifying authorities

- (1) A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
- (2) A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
- (3) A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
- (4) A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
- (5) A notifying authority shall safeguard the confidentiality of the information it obtains.
- (6) A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 25 [Article R16 of Decision No 768/2008/EC]

Information obligation of notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 26 [Article R17 of Decision No 768/2008/EC]

Requirements relating to notified bodies

(1) For the purposes of notification, a notified body shall meet the requirements laid down in paragraphs 2 to 11.

- (2) A conformity assessment body shall be established under national law of a Member State and have legal personality.
- (3) A conformity assessment body shall be a third-party body independent of the organisation or the subsystem or the safety component it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of subsystems or safety components which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

(4) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the subsystems or the safety components which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed subsystems or safety components that are necessary for the operations of the conformity assessment body or the use of such subsystems or safety components for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those subsystems or safety components, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

- (5) Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
- (6) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes IV to VIII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of subsystems or safety components in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the subsystem or safety component technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment tasks in an appropriate manner and shall have access to all necessary equipment or facilities.

- (7) The personnel responsible for carrying out conformity assessment activities shall have the following:
 - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified:
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the essential requirements set out in Annex II, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
 - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
- (8) The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and of the personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

- (9) Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
- (10) The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes IV to VIII or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
- (11) Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under this Regulation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 27 [Article R18 of Decision No 768/2008/EC]

Presumption of conformity

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been

published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 26 in so far as the applicable harmonised standards cover those requirements.

Article 28 [Article R20 of Decision No 768/2008/EC]

Subsidiaries of and subcontracting by notified bodies

- (1) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 26 and shall inform the notifying authority accordingly.
- (2) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
- (3) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
- (4) Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes IV to VIII.

Article 29 [Article R22 of Decision No 768/2008/EC]

Application for notification

- (1) A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
- (2) The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the subsystem/safety component or subsystems/safety components for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.
- (3) Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

Article 30 [Article R23 of Decision No 768/2008/EC]

Notification procedure

- (1) Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 26.
- (2) They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
- (3) The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the subsystem/safety component or subsystems/safety components concerned and the relevant attestation of competence.
- (4) Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other

Member States with documentary evidence which attests the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26.

(5) The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Regulation.

(6) The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 31 [Article R24 of Decision No 768/2008/EC]

Identification numbers and lists of notified bodies

(1) The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

(2) The Commission shall make publicly available the list of the notified bodies under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

Article 32 [Article R25 of Decision No 768/2008/EC]

Changes to notifications

- (1) Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26 or that it is failing to fulfil its obligations, the notifying authority shall, as appropriate, restrict, suspend or withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
- (2) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 33 [Article R26 of Decision No 768/2008/EC]

Challenge of the competence of notified bodies

(1) The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

- (2) The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.
- (3) The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
- (4) Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

The implementing act referred to in the first subparagraph shall be adopted in accordance with the advisory procedure referred to in Article 39(2).

Article 34 [Article R27 of Decision No 768/2008/EC]

Operational obligations of notified bodies

- (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes IV to VIII.
- (2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.
 - Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the subsystem or safety component technology in question and the mass or serial nature of the production process.
 - In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the subsystem or the safety component with the provisions of this Regulation.
- (3) Where a notified body finds that essential requirements set out in Annex II or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.
- (4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a subsystem or a safety component no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
- (5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 35

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of notified bodies is available.

Article 36 [Article R28 of Decision No 768/2008/EC]

Information obligation of notified bodies

- (1) Notified bodies shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of a certificate;
 - (b) any circumstances affecting the scope of or the conditions for notification;
 - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
- (2) Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same subsystems or safety components with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 37 [Article R29 of Decision No 768/2008/EC]

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 38 [Article R30 of Decision No 768/2008/EC]

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.

CHAPTER V

COMMITTEE PROCEDURE, TRANSITIONAL AND FINAL PROVISIONS

Article 39

Committee procedure

- (1) The Commission shall be assisted by the Committee on cableway installations. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- (2) Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Article 40

Penalties

The Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation and shall take all measures necessary

to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

The Member States shall notify those provisions to the Commission by [3 months prior to the date referred to in Article 43(2)] and shall notify it without delay of any subsequent amendment affecting them.

Article 41

Transitional provisions

Member States shall not impede the making available on the market of subsystems or safety components covered by Directive 2000/9/EC which are in conformity with that Directive and which were placed on the market before [the date referred to in Article 43(2)].

Member States shall not impede the entry into service of cableway installations covered by Directive 2000/9/EC which are in conformity with that Directive and which were constructed before [the date referred to in Article 43(2)].

Article 42

Repeal

Directive 2000/9/EC is repealed from [the date referred to in Article 43(2)].

References to the repealed Directive shall be construed as references to this Regulation and shall be read with in accordance with the correlation table laid down in Annex X.

Article 43

Entry into force and date of application

- (1) This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.
- (2) It shall apply from [two years after entry into force].
- (3) By way of derogation from paragraph 2, Articles 22 to 38 shall apply from [six months after entry into force].

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the European Parliament The President For the Council The President