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[1] Text with EEA relevance

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

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

I

(Legislative acts)

DIRECTIVES

DIRECTIVE 2014/51/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

amending Directives 2003/71/EC and 2009/138/EC and Regulations (EC) No 1060/2009, (EU) No 1094/2010 and (EU) No 1095/2010 in respect of the powers of the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority)

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 Articles 50, 53, 62, and 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 Central Bank [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Acting in accordance with the ordinary legislative procedure [3],

Whereas:

(1) The financial crisis in 2007 and 2008 exposed important shortcomings in financial supervision, both in particular cases and in relation to the financial system as a whole. Nationally based supervisory models have lagged behind financial globalisation and the integrated and interconnected reality of European financial markets, in which many financial institutions operate across borders. The crisis exposed shortcomings in the areas of cooperation, coordination, consistent application of Union law and trust between national competent authorities.

(2) In a number of resolutions adopted before and during the financial crisis, the European Parliament called for a move towards more integrated European supervision in order to ensure a truly level playing field for all actors at Union level, and for such supervision to reflect the increasing integration of financial markets in the Union, in particular in its resolutions of 13 April 2000 on the Commission communication on implementing the framework for financial markets: Action Plan, of 21 November 2002 on prudential supervision rules in the European Union, of 11 July 2007 on financial services policy (2005-2010) — White Paper, of 23 September 2008 with recommendations to the Commission on hedge funds and private equity, of 9 October 2008 with recommendations to the Commission on Lamfalussy follow-up: future structure of supervision, and in its positions of 22 April 2009 on the amended proposal for a directive of the European Parliament and of the Council on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II), and of 23 April 2009 on the proposal for a regulation of the European Parliament and of the Council on Credit Rating Agencies.

[1] OJ C 159, 28.5.2011, p. 10.
[2] OJ C 218, 23.7.2011, p. 82.
[3] Position of the European Parliament of 11 March 2014 (not yet published in the Official Journal) and Decision of the Council of 14 April 2014.

(3) In November 2008 the Commission instructed a High-Level Group chaired by Jacques de Larosière to make recommendations on how to strengthen European supervisory arrangements with a view to better protecting Union citizens and rebuilding trust in the financial system. In its final report presented on 25 February 2009 (the 'de Larosière Report'), the High-Level Group recommended that the supervisory framework be strengthened to reduce the risk and severity of future financial crises. It recommended far-reaching reforms to the supervisory structure of the financial sector within the Union. The de Larosière Report also recommended that a European system of financial supervision be created, comprising three European supervisory authorities — one for each of the banking, the securities and the insurance and the occupational pensions sectors — and a European systemic risk council.

(4) Financial stability is a prerequisite for the real economy to provide jobs, credit and growth. The financial crisis has revealed serious shortcomings in financial supervision, which has failed to anticipate adverse macro-prudential developments or to prevent the accumulation of excessive risks within the financial system.

(5) In the conclusions following its meeting of 18 and 19 June 2009, the European Council recommended that a European system of financial supervisors comprising three new European supervisory authorities be established. It also recommended that the system should aim to upgrade the quality and consistency of national supervision, strengthening the oversight of cross-border groups, establishing a single European rulebook applicable to all financial institutions in the internal market. It emphasised that the European supervisory authorities (the 'ESAs') should also enjoy supervisory powers in respect of credit rating agencies, and invited the Commission to prepare concrete proposals as to how the European System of Financial Supervision ('ESFS') could play a strong role in crisis situations.

(6) In 2010, the European Parliament and the Council adopted three Regulations establishing the ESAs: Regulation (EU) No 1093/2010 of the European Parliament and of the Council ([1]) establishing the European Supervisory Authority (European Banking Authority), Regulation (EU) No 1094/2010 of the European Parliament and of the Council ([2])establishing the European Supervisory Authority (European Insurance and Occupational Pensions Authority) ('EIOPA'), and Regulation (EU) No 1095/2010 of the European Parliament and of the Council ([3]) establishing the European Supervisory Authority (European Securities and Markets Authority) ('ESMA') as part of the ESFS.

(7) In order for the ESFS to work effectively, changes to the Union legislative acts in the field of operation of the three ESAs are necessary. Such changes concern the definition of the scope of certain powers of the ESAs, the integration of certain powers in existing processes established in relevant Union legislative acts and amendments to ensure a smooth and effective functioning of the ESAs in the context of the ESFS.

(8) The establishment of the ESAs should therefore be accompanied by the development of a single rulebook to ensure consistent harmonisation and uniform application and thus contribute to the even more effective functioning of the internal market and the more effective implementation of micro-level supervision. The regulations establishing the ESFS provide that the ESAs may develop draft technical standards in the areas specifically set out in the relevant legislation, to be submitted to the Commission for adoption in accordance with Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU) by means of delegated or implementing acts. Whereas Directive 2010/78/EU of the European Parliament and of the Council ([4]) has identified a first set of such areas, this Directive should identify a further set of areas, in particular for Directives 2003/71/EC and 2009/138/EC of the European Parliament and of the Council ([5]), for Regulation (EC) No 1060/2009 of the European Parliament and of the Council ([6]) and for Regulations (EU) No 1094/2010 and (EU) No 1095/2010.

([1]) Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

([2]) Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

([3]) Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

([4]) Directive 2010/78/EU of the European Parliament and of the Council of 24 November 2010 in respect of the powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority) (OJ L 331, 15.12.2010, p. 120).

([5]) Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1).

([6]) Regulation (EC) No 1060/2009 of the European Parliament and of the Council of 16 September 2009 on credit rating agencies (OJ L 302, 17.11.2009, p. 1).

(9) The relevant legislative acts should establish areas in which the ESAs are empowered to develop draft technical standards and how such standards should be adopted. The relevant legislative acts should lay down the elements, conditions and specifications as detailed in Article 290 TFEU in the case of delegated acts.

(10) The identification of areas in which technical standards should be adopted should strike an appropriate balance between building a single set of harmonised rules and avoiding unduly complicated regulation and enforcement. The areas selected should be only those in which consistent technical rules will contribute significantly and effectively to the achievement of the objectives of the relevant legislative acts, while ensuring that policy decisions are taken by the European Parliament, the Council and the Commission in accordance with their usual procedures.

(11) Matters subject to technical standards should be genuinely technical, where their development requires the expertise of supervisory experts. Regulatory technical standards adopted as delegated acts pursuant to Article 290 TFEU should further develop, specify and determine the conditions for consistent harmonisation of the rules included in the legislative acts adopted by the European Parliament and the Council, supplementing or amending certain non-essential elements thereof. On the other hand, implementing technical standards adopted as implementing acts pursuant to Article 291 TFEU should establish conditions for the uniform application of legislative acts. Technical standards should not involve policy choices.

(12) In the case of regulatory technical standards it is appropriate to apply the procedure provided for in Articles 10 to 14 of Regulation (EU) No 1093/2010, of Regulation (EU) No 1094/2010, and of Regulation (EU) No 1095/2010, as appropriate. Implementing technical standards should be adopted in accordance with the procedure provided for in Article 15 of Regulation (EU) No 1093/2010, of Regulation (EU) No 1094/2010, and of Regulation (EU) No 1095/2010, as appropriate.

(13) Regulatory and implementing technical standards should contribute to a single rulebook for financial services law as endorsed by the European Council in its conclusions of June 2009. To the extent that certain requirements in Union legislative acts are not fully harmonised, and in accordance with the precautionary principle on supervision, regulatory and implementing technical standards developing, specifying or determining the conditions of application for those requirements should not prevent Member States from requiring additional information or imposing more stringent requirements. Regulatory and implementing technical standards should therefore allow Member States to require additional information or impose more stringent requirements in specific areas, where those legislative acts provide for such discretion.

(14) In accordance with Regulations (EU) No 1093/2010, (EU) No 1094/2010 and (EU) No 1095/2010, before submitting regulatory or implementing technical standards to the Commission, the ESAs should, where appropriate, conduct open public consultations relating to them and analyse the potential related costs and benefits.

(15) It should be possible for regulatory and implementing technical standards to provide for transitional measures subject to adequate deadlines, if the costs of immediate implementation would be excessive compared to the benefits involved.

(16) At the moment of adoption of this Directive, the work relating to the preparation of, and the consultation relating to, the first set of measures to implement the framework rules under Directive 2009/138/EC is well underway. In the interests of an early finalisation of those measures, it is appropriate to allow the Commission, for a transitional period, to adopt the regulatory technical standards provided for in this Directive, in accordance with the procedure for the adoption of delegated acts. Any amendments to such delegated acts or, after the transitional period has expired, any regulatory technical standards to implement Directive 2009/138/EC, should be adopted in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

(17) Furthermore, it is appropriate to allow EIOPA, after a transitional period of two years, to propose updates to a number of delegated acts in the form of regulatory technical standards. Those updates should be limited to technical aspects of the relevant delegated acts and should not imply strategic decisions or policy choices.

(18) When EIOPA is preparing and drafting regulatory technical standards to adjust delegated acts to technical developments on financial markets, the Commission should ensure simultaneous, timely and appropriate transmission of information on the scope of those draft regulatory technical standards to the European Parliament and to the Council.

(19) Regulations (EU) No 1093/2010, (EU) No 1094/2010 and (EU) No 1095/2010 provide for a mechanism to settle disagreements between national supervisory authorities. Where a national supervisory authority disagrees with the procedure or content of an action or inaction by another national supervisory authority in areas specified in Union legislative acts in accordance with those Regulations, and the relevant legislative act requires cooperation, coordination or joint decision-making by national supervisory authorities from more than one Member State, the ESA concerned, at the request of one of the national supervisory authorities concerned, should be able to assist the authorities in reaching an agreement within the time-limit set by the ESA which should take into account any relevant time-limits in the relevant legislation, and the urgency and complexity of the disagreement. In the event that such disagreement persists, the ESA should be able to settle the matter.

(20) Regulations (EU) No 1093/2010, (EU) No 1094/2010 and (EU) No 1095/2010 require that the cases where the mechanism to settle disagreements between national supervisory authorities may be applied are to be specified in the sectoral legislation. This Directive should identify a first set of such cases in the insurance and reinsurance sector, without prejudice to adding further cases in the future. This Directive should not prevent the ESAs from acting in accordance with other powers or fulfilling tasks specified in Regulations (EU) No 1093/2010, (EU) No 1094/2010 and (EU) No 1095/2010, including non-binding mediation and contributing to the consistent, efficient and effective application of Union law. Moreover, in those areas where some form of non-binding mediation is already established in the relevant law, or where there are time-limits for joint decisions to be taken by one or more national supervisory authorities, amendments are needed to ensure clarity and minimum disruption of the process for reaching a joint decision, but also to ensure that, where necessary, the ESAs should be able to resolve disagreements. The binding procedure for the settlement of disagreements is designed to solve situations where national supervisory authorities cannot resolve, among themselves, procedural or substantive issues relating to compliance with Union law.

(21) This Directive should therefore identify situations where a procedural or a substantive issue of compliance with Union law may need to be resolved and the national supervisory authorities may not be able to resolve the matter on their own. In such a situation, one of the national supervisory authorities concerned should be able to raise the issue with the ESA concerned. That ESA should act in accordance with its establishing regulation and with this Directive. It should be able to require that the national supervisory authorities concerned take specific action or refrain from action in order to settle the matter and ensure compliance with Union law, with binding effects on the national supervisory authorities concerned. In cases where the relevant legislative act of the Union confers discretion on Member States, decisions taken by an ESA should not replace the exercise of discretion by the national supervisory authorities, where that exercise is in accordance with Union law.

(22) Directive 2009/138/EC provides for joint decisions as regards the approval of applications to use an internal model at group and subsidiary levels, the approval of applications to make a subsidiary subject to Articles 238 and 239 of that Directive and the identification of the group supervisor on a different basis from the criteria set out in Article 247 thereof. In all of those areas, an amendment should clearly state that, in the event of disagreement, EIOPA may resolve the disagreement using the process laid down in Regulation (EU) No 1094/2010. That approach makes it clear that, while EIOPA should not replace the exercise of discretion by the national supervisory authorities, it should be possible for disagreements to be resolved and cooperation to be strengthened before a final decision is taken by the national supervisory authority or issued to an institution. EIOPA should resolve disagreements by mediating between the conflicting views of the national supervisory authorities.

(23) The new supervisory architecture established by the ESFS will require national supervisory authorities to cooperate closely with the ESAs. Amendments to the relevant legislative acts should ensure that there are no legal obstacles to the information-sharing obligations included in Regulations (EU) No 1093/2010, (EU) No 1094/2010 and (EU) No 1095/2010 and that the provision of data does not give rise to an unnecessary administrative burden.

(24) Insurance and reinsurance undertakings should be required only to provide such information to their national supervisory authorities that is relevant for the purposes of supervision, taking into account the objectives of supervision as laid down in Directive 2009/138/EC. Information on a full list of assets to be provided on an item-by-item basis and other information to be provided more frequently than annually should be required only where the additional knowledge obtained by the national supervisory authorities for the purpose of monitoring the financial health of the undertakings, or taking into account the potential impacts of their decisions on financial stability, outweighs the burden associated with the calculation and submission of that information. After assessing the nature, scale and complexity of the risks inherent in the business of the undertaking, national supervisory authorities should have the power to allow limitations on the frequency and the scope of information to be reported or to exempt from reporting on an item-by-item basis only where that undertaking does not exceed specific thresholds. It should be ensured that the smallest undertakings are eligible for limitations and exemption and that those undertakings do not represent more than 20 % of a Member State's life and non-life insurance or of its reinsurance market.

(25) In order to ensure that the information reported by participating insurance and reinsurance undertakings or insurance holding companies at the level of the group is accurate and complete, national supervisory authorities should not allow limitations on the information to be reported or exempt from reporting on an item-by-item basis undertakings which belong to a group, unless the national supervisory authority is satisfied that reporting would be inappropriate given the nature, scale and complexity of the risks inherent in the business of the group.

(26) In areas where the Commission is currently empowered by Directive 2009/138/EC to adopt implementing measures, where those measures are non-legislative acts of general application to supplement or amend certain non-essential elements of that Directive in the sense of Article 290 TFEU, the Commission should be empowered to adopt delegated acts in accordance with that Article or regulatory technical standards in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

(27) In order to ensure that the same treatment is applied to all insurance and reinsurance undertakings calculating the Solvency Capital Requirement (SCR) pursuant to Directive 2009/138/EC on the basis of the standard formula, or to take account of market developments, the Commission should be empowered to adopt delegated acts in relation to the calculation of the SCR on the basis of the standard formula.

(28) Where risks are not adequately covered by a sub-module, EIOPA should be empowered to develop draft regulatory technical standards in relation to quantitative limits and asset eligibility criteria for the SCR on the basis of the standard formula.

(29) In order to allow for the consistent calculation of technical provisions by insurance and reinsurance undertakings under Directive 2009/138/EC, it is necessary for a central body to derive, publish, and update certain technical information relating to the relevant risk-free interest rate term structure on a regular basis, taking account of observations in the financial market. The manner in which the relevant risk-free interest rate term structure is derived should be transparent. Given the technical and insurance-related nature of those tasks, they should be carried out by EIOPA.

(30) The relevant risk-free interest rate term structure should avoid artificial volatility of technical provisions and eligible own funds and provide an incentive for good risk management. The choice of the starting point of the extrapolation of risk-free interest rates should allow undertakings to match with bonds the cash flows which are discounted with non-extrapolated interest rates in the calculation of the best estimate. Under market conditions similar to those at the date of entry into force of this Directive, the starting point for the extrapolation of risk-free interest rates, in particular for the euro, should be at a maturity of 20 years. Under market conditions similar to those at the date of entry into force of this Directive, the extrapolated part of the relevant risk-free interest rate term structure, in particular for the euro, should converge in such a way to the ultimate forward rate that for maturities 40 years past the starting point of the extrapolation the extrapolated forward rates do not differ more

than three basis points from the ultimate forward rate. For currencies other than the euro, the characteristics of the local bond and swap markets should be taken into account when determining the starting point for the extrapolation of risk-free interest rates and the appropriate convergence period to the ultimate forward rate.

(31) Where insurance and reinsurance undertakings hold bonds or other assets with similar cash flow characteristics to maturity, they are not exposed to the risk of changing spreads on those assets. In order to avoid changes of asset spreads from impacting on the amount of own funds of those undertakings, they should be allowed to adjust the relevant risk-free interest rate term structure for the calculation of the best estimate in line with the spread movements of their assets. The application of such a matching adjustment should be subject to supervisory approval and strict requirements on the assets and liabilities should ensure that the insurance and reinsurance undertakings can hold their assets to maturity. In particular the cash flows of assets and liabilities should be matched and the assets should be replaced for the purpose of retaining the matching only where the expected cash flows have materially changed such as in the case of the downgrade or default of a bond. Insurance and reinsurance undertakings should publicly disclose the impact of the matching adjustment on their financial position to ensure adequate transparency.

(32) In order to prevent pro-cyclical investment behaviour, insurance and reinsurance undertakings should be allowed to adjust the relevant risk-free interest rate term structure for the calculation of the best estimate of technical provisions to mitigate the effect of exaggerations of bond spreads. Such a volatility adjustment should be based on reference portfolios for the relevant currencies of those undertakings and, where necessary to ensure representativeness, on reference portfolios for national insurance markets. Insurance and reinsurance undertakings should publicly disclose the impact of the volatility adjustment on their financial position to ensure adequate transparency.

(33) In view of the importance of discounting for the calculation of technical provisions, Directive 2009/138/EC should ensure uniform conditions for the choice of discount rates by insurance and reinsurance undertakings. In order to ensure such uniform conditions, implementing powers should be conferred on the Commission to lay down relevant risk-free interest rate term structures to calculate the best estimate, fundamental spreads for the calculation of the matching adjustment and of the volatility adjustments. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([1]). Those implementing acts should make use of technical information derived from and published by EIOPA. The advisory procedure should be used for the adoption of those implementing acts.

(34) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the relevant risk-free interest rate term structure, imperative grounds of urgency so require.

(35) In order to mitigate undue potential pro-cyclical effects, the period for restoring compliance with the SCR should be extended in exceptional adverse situations, including in the case of steep falls in financial markets, persistent low interest rate environments and high-impact catastrophic events, affecting insurance and reinsurance undertakings representing a significant share of the market or affected lines of business. EIOPA should be responsible for declaring the existence of exceptional adverse situations and the Commission should be empowered to adopt measures by means of delegated and implementing acts specifying the criteria and the relevant procedures.

(36) In the context of the matching adjustment to the relevant risk-free interest rate term structure provided for pursuant to this Directive, the requirement that the portfolio of insurance or reinsurance obligations to which the matching adjustment is applied and the assigned portfolio of assets are identified, organised and managed separately from other activities of the undertakings and that those assets cannot be used to cover losses arising from other activities of the undertakings should be understood in an economic sense. It should not imply a requirement on Member States to have a legal concept of a ring-fenced fund in national legislation. Undertakings that use the matching adjustment should identify, organise and manage the portfolio of assets and obligations separately from other parts of the business and should not therefore be permitted to meet risks arising elsewhere in

([1]) 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 Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

the business using the assigned portfolio of assets. While this allows efficient portfolio management, the reduced transferability and scope for diversification between the assigned portfolio and the remainder of the undertaking need, for the purposes of the matching adjustment, to be reflected in adjustments to own funds and the SCR.

(37) The spread on the reference portfolio referred to in this Directive should be determined in a transparent manner using relevant indices where available.

(38) In order to ensure the transparent application of the volatility adjustment, the matching adjustment and the transitional measures on risk-free interest rates and on technical provisions provided for pursuant to this Directive, insurance and reinsurance undertakings should publicly disclose the impact of not applying these measures on their financial positions, including on the amount of technical provisions, the SCR, the Minimum Capital Requirement (MCR) pursuant to Directive 2009/138/EC, the basic own funds and the amounts of own funds eligible to cover the MCR and the SCR.

(39) Member States should be able in their national legislation to grant their national supervisory authorities the power to allow, and, in exceptional circumstances, to reject, the use of the volatility adjustment.

(40) In order to ensure that certain technical inputs to the SCR using the standard formula are provided on a harmonised basis, for instance to allow for harmonised approaches to the use of ratings, specific tasks should be assigned to EIOPA. Recognition of credit rating agencies should be aligned and made consistent with Regulation (EC) No 1060/2009, Regulation (EU) No 575/2013 of the European Parliament and of the Council [1] and Directive 2013/36/EU of the European Parliament and of the Council [2]. Overlap with Regulation (EC) No 1060/2009 should be avoided and to that end a role for the Joint Committee of European Supervisory Authorities established by Regulations (EU) No 1093/2010, (EU) No 1094/2010 and (EU) No 1095/2010 is justified. EIOPA should make optimal use of ESMA's competence and experience. The detailed manner in which such tasks are to be performed should be further specified in measures to be adopted by delegated or implementing acts.

(41) Lists of regional governments and local authorities published by EIOPA should not be more detailed than is necessary to ensure that such governments or authorities are granted the same treatment only where the risks of the exposure are the same as for central governments.

(42) In order to ensure a harmonised approach under Directive 2009/138/EC for determining when an extension of the recovery period in cases of breaches of the SCR is permitted, the conditions which constitute an exceptional adverse situation should be specified. EIOPA should be responsible for declaring the existence of such exceptional adverse situations and the Commission should be empowered to adopt measures by means of delegated and implementing acts specifying the criteria and the relevant procedures in the case of such exceptional adverse situations.

(43) In order to ensure cross-sectoral consistency and to remove the misalignment between the interests of undertakings that 'repackage' loans into tradable securities and other financial instruments (originators or sponsors) and the interests of insurance or reinsurance undertakings that invest in such securities or instruments, the Commission should be empowered to adopt measures by means of delegated acts in the context of investments in repackaged loans under Directive 2009/138/EC, specifying not only the requirements but also the consequences of breaching those requirements.

(44) In order to allow for greater convergence of procedures for supervisory approvals provided for in Directive 2009/138/EC of undertaking specific parameters, model change policies, special purpose vehicles and the setting and removal of capital add-ons, the Commission should be empowered to adopt measures by means of delegated acts specifying the relevant procedure in those areas.

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[1] Regulation (EU) No 575/2010 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

[2] Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).

(45) The development by the International Association of Insurance Supervisors of a global, risk-based solvency standard is ongoing and continues to foster greater supervisory coordination and cooperation internationally. The provisions in Directive 2009/138/EC relating to Commission delegated acts determining the equivalence of third-country solvency and prudential regimes are consistent with the objectives of encouraging international convergence towards the introduction of risk-based solvency and prudential regimes. In order to acknowledge that some third countries may need more time to adapt and implement solvency and prudential regimes that would fully satisfy the criteria for being recognised as equivalent, it is necessary to specify conditions in relation to the treatment of such third-country regimes in order for those third countries to be recognised temporarily as equivalent. Commission delegated acts determining temporary equivalence should, where appropriate, take into account international developments. Where the Commission determines that a third country's prudential regime for group supervision is temporarily equivalent, additional supervisory reporting should be allowed for in order to ensure the protection of policy holders and beneficiaries within the Union.

(46) Given the particular nature of the insurance market, in order to ensure a level playing field for insurance and reinsurance undertakings established in third countries, whether their parent undertaking is established in the Union or not, the Commission should be able to determine that a third country is provisionally equivalent for the purposes of calculating the group solvency requirements and the eligible own funds to satisfy those requirements.

(47) In order to ensure that interested stakeholders are properly informed about the structure of insurance and reinsurance groups, it is necessary that information on their legal structure and the governance and organisational structure is made available to the public. That information should include at least information on the legal name, type of business and country of establishment of subsidiaries, material related undertakings and significant branches.

(48) Commission decisions to the effect that a third country's solvency or prudential regime is fully or temporarily equivalent should take into account, where relevant, the existence, duration and nature of transitional measures in those third-country regimes.

(49) In order to enable the European Cooperative Society, established by Council Regulation (EC) No 1435/2003 [1], to provide insurance and reinsurance services, it is necessary to extend the list of permissible legal forms of insurance and reinsurance undertakings under Directive 2009/138/EC to include the European Cooperative Society.

(50) The amounts in euro of the MCR floor for insurance and reinsurance undertakings should be adapted. Such an adaptation arises out of the periodic adjustment of the existing capital requirement floors for such undertakings to take account of inflation.

(51) The calculation of the SCR for health insurance should reflect national equalisation systems and should also account for changes in the national health legislation, as they are a fundamental part of the insurance system within those national health markets.

(52) Certain implementing powers established pursuant to Article 202 of the Treaty establishing the European Community (EC Treaty) should be replaced by appropriate provisions pursuant to Article 290 TFEU.

(53) The alignment of comitology procedures to the TFEU and, in particular, to Article 290 thereof, should be effected on a case-by-case basis. In order to take account of the technical developments in the financial markets and to specify the requirements laid down in the directives amended by this Directive, the Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU. In particular, delegated acts should be adopted in respect of details concerning governance requirements, valuation, supervisory reporting and public disclosure, the determination and classification of own funds, the standard formula for the calculation of the SCR (including any consequential changes in the area of capital add-ons) and the choice of methods and assumptions for the calculation of technical provisions.

[1] Council Regulation (EC) No 1435/2003 of 22 July 2003 on the Statute for a European Cooperative Society (SCE) (OJ L 207, 18.8.2003, p. 1).

(54) In Declaration No 39 on Article 290 of the Treaty on the Functioning of the European Union, annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, the Conference took note of the Commission's intention to continue to consult experts appointed by the Member States in the preparation of draft delegated acts in the financial services area in accordance with its established practice.

(55) The European Parliament and the Council should have three months from the date of notification to object to a delegated act. At the initiative of the European Parliament or of the Council, it should be possible to prolong that period by three months with regard to significant areas of concern. It should also be possible for the European Parliament and the Council to inform the other institutions of their intention not to raise objections. Such early approval of delegated acts is particularly appropriate when deadlines need to be met, for example where there are timetables in the basic act for the Commission to adopt delegated acts.

(56) In the light of the financial crisis and the pro-cyclical mechanisms that contributed to its origin and aggravated its effect, the Financial Stability Board, the Basel Committee on Banking Supervision, and the G20 made recommendations to mitigate the pro-cyclical effects of financial regulation. Those recommendations are of direct relevance to insurance and reinsurance undertakings as important components of the financial system.

(57) In order to achieve coherent application of this Directive and to assure macro-prudential oversight across the Union, it is appropriate that the European Systemic Risk Board, established by Regulation (EU) No 1092/2010 of the European Parliament and of the Council [1], develop principles tailored for the Union economy.

(58) The financial crisis highlighted the fact that financial institutions greatly underestimated the level of counterparty credit risk associated with over-the-counter (OTC) derivatives. This prompted the G20, in September 2009, to call for more OTC derivatives to be cleared through a central counterparty. Furthermore, they asked to subject those OTC derivatives that could not be cleared centrally to higher capital requirements in order to reflect properly the higher risks associated with them.

(59) The calculation of the standard formula for the SCR should treat exposures to qualifying central counterparties consistently with the treatment of such exposures in the capital requirements for credit institutions and financial institutions, as defined in Article 4(1) of Regulation (EU) No 575/2013, specifically with regard to differences in the treatment between qualifying central counterparties and other counterparties.

(60) In order to ensure that the Union's objective of long-term sustainable growth and the objectives of Directive 2009/138/EC of primarily protecting policy holders and also ensuring financial stability, continue to be met, the Commission should review the appropriateness of the methods, assumptions and standard parameters used when calculating the standard formula for the SCR within five years of the application of Directive 2009/138/EC. The review should, in particular, be based on the overall experience of insurance and reinsurance undertakings using the standard formula for the SCR during the transitional period. The review should also take into account the performance of any asset class and financial instruments, the behaviour of investors in those assets and financial instruments as well as developments in international standard setting in financial services. The review of the standard parameters for certain asset classes, such as fixed-income securities and long-term infrastructure, may need to be prioritised.

(61) In order to allow for a smooth transition under Directive 2009/138/EC to a new regime, it is necessary to provide for phasing in and specific transitional measures. The transitional measures should aim to avoid market disruption and limiting interferences with existing products as well as ensuring the availability of insurance products. The transitional measures should encourage undertakings to move towards compliance with the particular requirements of the new regime as soon as possible.

[1] Regulation (EU) No 1092/2010 of the European Parliament and of the Council of 24 November 2010 on European Union macro-prudential oversight of the financial system and establishing a European Systemic Risk Board (OJ L 331, 15.12.2010, p. 1).

(62) It is necessary to provide for a transitional regime for occupational retirement business carried out by insurance undertakings pursuant to Article 4 of Directive 2003/41/EC of the European Parliament and of the Council [1] while the Commission conducts its review of that Directive. The transitional regime should lapse as soon as amendments to Directive 2003/41/EC enter into force.

(63) Notwithstanding the anticipated application of Directive 2009/138/EC, particularly for the purposes of assessments relating to the approval of internal models, ancillary own funds, classification of own funds, undertaking specific parameters, special purpose vehicles, the duration based equity risk sub-module, and the transitional provision on the calculation of the best estimate with respect to insurance or reinsurance obligations corresponding to paid-in premiums for existing contracts, Council Directives 64/225/EEC [2], 73/239/EEC [3], 73/240/EEC [4], 76/580/EEC [5], 78/473/EEC [6], 84/641/EEC [7], 87/344/EEC [8], 88/357/EEC [9] and 92/49/EEC [10], and Directives 98/78/EC [11], 2001/17/EC [12], 2002/83/EC [13] and 2005/68/EC [14] of the European Parliament and of the Council (collectively referred to as 'Solvency I'), as amended by the acts listed in Part A of Annex VI of Directive 2009/138/EC, should continue to apply until the end of 2015.

(64) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive and to Directive 2009/138/EC, the legislator considers the transmission of such documents to be justified.

(65) Since the objectives of this Directive, namely improving the functioning of the internal market by means of ensuring a high, effective and consistent level of prudential regulation and supervision, protecting policy holders and beneficiaries and thereby businesses and consumers, protecting the integrity, efficiency and orderly functioning of financial markets, maintaining the stability of the financial system, and strengthening international supervisory coordination, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale, 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 Directive does not go beyond what is necessary in order to achieve those objectives.

(66) Directives 2003/71/EC and 2009/138/EC and Regulations (EC) No 1060/2009, (EU) No 1094/2010 and (EU) No 1095/2010 should therefore be amended accordingly,

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(1) Directive 2003/41/EC of the European Parliament and of the Council of 3 June 2003 on the activities and supervision of institutions for occupational retirement provision (OJ L 235, 23.9.2003, p. 10).

(2) Council Directive 64/225/EEC of 25 February 1964 on the abolition of restrictions on freedom of establishment and freedom to provide services in respect of reinsurance and retrocession (OJ 56, 4.4.1964, p. 878).

(3) First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance (OJ L 228, 16.8.1973, p. 3).

(4) Council Directive 73/240/EEC of 24 July 1973 abolishing restrictions on freedom of establishment in the business of direct insurance other than life assurance (OJ L 228, 16.8.1973, p. 20).

(5) Council Directive 76/580/EEC of 29 June 1976 amending Directive 73/239/EEC on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of direct insurance other than life assurance (OJ L 189, 13.7.1976, p. 13).

(6) Council Directive 78/473/EEC of 30 May 1978 on the coordination of laws, regulations and administrative provisions relating to Community co-insurance (OJ L 151, 7.6.1978, p. 25).

(7) Council Directive 84/641/EEC of 10 December 1984 amending, particularly as regards tourist assistance, the First Directive (73/239/EEC) on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance (OJ L 339, 27.12.1984, p. 21).

(8) Council Directive 87/344/EEC of 22 June 1987 on the coordination of laws, regulations and administrative provisions relating to legal expenses insurance (OJ L 185, 4.7.1987, p. 77).

(9) Second Council Directive 88/357/EEC of 22 June 1988 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and laying down provisions to facilitate the effective exercise of freedom to provide services and amending Directive 73/239/EEC (OJ L 172, 4.7.1988, p. 1).

(10) Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (third non-life insurance Directive) (OJ L 228, 11.8.1992, p. 1).

(11) Directive 98/78/EC of the European Parliament and of the Council of 27 October 1998 on the supplementary supervision of insurance undertakings in an insurance group (OJ L 330, 5.12.1998, p. 1).

(12) Directive 2001/17/EC of the European Parliament and of the Council of 19 March 2001 on the reorganisation and winding-up of insurance undertakings (OJ L 110, 20.4.2001, p. 28).

(13) Directive 2002/83/EC of the European Parliament and of the Council of 5 November 2002 concerning life assurance (OJ L 345, 19.12.2002, p. 1).

(14) Directive 2005/68/EC of the European Parliament and of the Council of 16 November 2005 on reinsurance and amending Council Directives 73/239/EEC, 92/49/EEC as well as Directives 98/78/EC and 2002/83/EC (OJ L 323, 9.12.2005, p. 1).

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2003/71/EC

Directive 2003/71/EC is amended as follows:

(1) in Article 5(4), the third subparagraph is replaced by the following:

'Where the final terms of the offer are neither included in the base prospectus, nor in a supplement, they shall be made available to investors, filed with the competent authority of the home Member State, and communicated by that competent authority to the competent authority of the host Member State(s) as soon as practicable upon the making of a public offer and, where possible, before the beginning of the public offer or admission to trading. The competent authority of the home Member State shall communicate those final terms to ESMA. The final terms shall contain only information that relates to the securities note and shall not be used to supplement the base prospectus. Article 8(1)(a) shall apply in such cases.';

(2) in Article 11, paragraph 3 is replaced by the following:

'3. In order to ensure consistent harmonisation in relation to this Article, ESMA shall develop draft regulatory technical standards to specify the information to be incorporated by reference.

ESMA shall submit those draft regulatory technical standards to the Commission by 1 July 2015.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.';

(3) in Article 13, paragraph 7 is replaced by the following:

'7. In order to ensure consistent harmonisation in relation to the approval of prospectuses, ESMA shall develop draft regulatory technical standards to specify the procedures for the approval of the prospectus and the conditions in accordance with which time limits may be adjusted.

ESMA shall submit those draft regulatory technical standards to the Commission by 1 July 2015.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.';

(4) in Article 14, paragraph 8 is replaced by the following:

'8. In order to ensure consistent harmonisation in relation to this Article, ESMA shall develop draft regulatory technical standards to specify the provisions relating to the publication of the prospectus in paragraphs 1 to 4.

ESMA shall submit those draft regulatory technical standards to the Commission by 1 July 2015.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.';

(5) in Article 15, paragraph 7 is replaced by the following:

'7. In order to ensure consistent harmonisation in relation to this Article, ESMA shall develop draft regulatory technical standards to specify the provisions concerning the dissemination of advertisements announcing the intention to offer securities to the public or the admission to trading on a regulated market, in particular before the prospectus has been made available to the public or before the opening of the subscription, and specify the provisions laid down in paragraph 4.

ESMA shall submit those draft regulatory technical standards to the Commission by 1 July 2015.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1095/2010.';

(6) the following article is inserted:

'Article 31a

Staff and resources of ESMA

ESMA shall asses the staffing and resources needs arising from the assumption of its powers and duties in accordance with this Directive and shall submit a report to the European Parliament, the Council and the Commission in relation thereto.'.

Article 2

Amendments to Directive 2009/138/EC

Directive 2009/138/EC is amended as follows:

(1) Article 13 is amended as follows:

(a) the following point is inserted after point (32):

'(32a) "qualifying central counterparty" means a central counterparty that has been either authorised in accordance with Article 14 of Regulation (EU) No 648/2012 of the European Parliament and of the Council (*) or recognised in accordance with Article 25 of that Regulation;

(*) Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories (OJ L 201, 27.7.2012, p. 1).';

(b) the following point is added:

'(40) "external credit assessment institution" or "ECAI" means a credit rating agency that is registered or certified in accordance with Regulation (EC) No 1060/2009 of the European Parliament and of the Council (**) or a central bank issuing credit ratings which are exempt from the application of that Regulation.

(**) Regulation (EC) No 1060/2009 of the European Parliament and of the Council of 16 September 2009 on credit rating agencies (OJ L 302, 17.11.2009, p. 1).';

(2) in Article 17, paragraph 3 is replaced by the following:

'3. The Commission may adopt delegated acts in accordance with Article 301a relating to the lists of forms set out in Annex III, excluding points 28 and 29 of each of Parts A, B and C.';

(3) the following article is inserted:

'Article 25a

Notification and publication of authorisations or withdrawals of authorisation

Every authorisation or withdrawal of authorisation shall be notified to the European Supervisory Authority (European Insurance and Occupational Pensions Authority) ("EIOPA") established by Regulation (EU) No 1094/2010 of the European Parliament and of the Council (***). The name of each insurance or reinsurance undertaking to which authorisation has been granted shall be entered on a list. EIOPA shall publish and keep up to date that list on its website.

(***) Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48.';

(4) in Article 29, paragraph 4 is replaced by the following:

'4. The delegated acts and the regulatory and implementing technical standards adopted by the Commission shall take into account the principle of proportionality, thus ensuring the proportionate application of this Directive, in particular in relation to small insurance undertakings.

The draft regulatory technical standards submitted by EIOPA in accordance with Article 10 to 14 of Regulation (EU) No 1094/2010, the draft implementing technical standards submitted in accordance with Article 15 thereof and the guidelines and recommendations issued in accordance with Article 16 thereof, shall take into account the principle of proportionality, thus ensuring the proportionate application of this Directive, in particular in relation to small insurance undertakings.';

(5) in Article 31, paragraph 4 is replaced by the following:

'4. Without prejudice to Article 35, Article 51, Article 254(2) and Article 256, the Commission shall adopt delegated acts in accordance with Article 301a relating to paragraph 2 of this Article, specifying the key aspects on which aggregate statistical data are to be disclosed, and the contents list and publication date of the disclosures.

5. In order to ensure uniform conditions relating to the application of paragraph 2 of this Article, and without prejudice to Article 35, Article 51, Article 254(2) and Article 256, EIOPA shall develop draft implementing technical standards to specify the templates and structure of the disclosure provided for in this Article.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 September 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(6) in Article 33, the following paragraphs are added:

'Where a supervisory authority has informed the supervisory authorities of a host Member State that it intends to carry out on-site verifications in accordance with the first paragraph and where that supervisory authority is prohibited from exercising its right to carry out those on-site verifications or where the supervisory authorities of the host Member State are unable in practice to exercise their right to participate in accordance with the second paragraph, the supervisory authorities may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.

In accordance with Article 21 of Regulation (EU) No 1094/2010, EIOPA may participate in on-site examinations where they are carried out jointly by two or more supervisory authorities.';

(7) Article 35 is amended as follows:

(a) in paragraph 1, the introductory part is replaced by the following:

'1. Member States shall require insurance and reinsurance undertakings to submit to the supervisory authorities the information which is necessary for the purposes of supervision, taking into account the objectives of supervision laid down in Articles 27 and 28. Such information shall include at least the information necessary for the following when performing the process referred to in Article 36:';

(b) paragraph 6 is replaced by the following:

'6. Without prejudice to Article 129(4), where the predefined periods referred to in paragraph 2(a)(i) are shorter than one year, the supervisory authorities concerned may limit regular supervisory reporting, where:

(a) the submission of that information would be overly burdensome in relation to the nature, scale and complexity of the risks inherent in the business of the undertaking;

(b) the information is reported at least annually.

Supervisory authorities shall not limit regular supervisory reporting with a frequency shorter than one year in the case of insurance or reinsurance undertakings that are part of a group within the meaning of Article 212(1)(c), unless the undertaking can demonstrate to the satisfaction of the supervisory authority that regular supervisory reporting with a frequency shorter than one year is inappropriate, given the nature, scale and complexity of the risks inherent in the business of the group.

The limitation to regular supervisory reporting shall be granted only to undertakings that do not represent more than 20 % of a Member State's life and non-life insurance and reinsurance market respectively, where the non-life market share is based on gross written premiums and the life market share is based on gross technical provisions.

Supervisory authorities shall give priority to the smallest undertakings when determining the eligibility of the undertakings for those limitations.

7. The supervisory authorities concerned may limit regular supervisory reporting or exempt insurance and reinsurance undertakings from reporting on an item-by-item basis, where:

(a) the submission of that information would be overly burdensome in relation to the nature, scale and complexity of the risks inherent in the business of the undertaking;

(b) the submission of that information is not necessary for the effective supervision of the undertaking;

(c) the exemption does not undermine the stability of the financial systems concerned in the Union; and

(d) the undertaking is able to provide the information on an ad-hoc basis.

Supervisory authorities shall not exempt from reporting on an item-by-item basis insurance or reinsurance undertakings that are part of a group within the meaning of Article 212(1)(c), unless the undertaking can demonstrate to the satisfaction of the supervisory authority that reporting on an item-by-tem basis is inappropriate, given the nature, scale and complexity of the risks inherent in the business of the group and taking into account the objective of financial stability.

The exemption from reporting on an item-by-item basis shall be granted only to undertakings that do not represent more than 20 % of a Member State's life and non-life insurance or reinsurance market respectively, where the non-life market share is based on gross written premiums and the life market share is based on gross technical provisions.

Supervisory authorities shall give priority to the smallest undertakings when determining the eligibility of the undertakings for those exemptions.

8. For the purposes of paragraphs 6 and 7, as part of the supervisory review process, supervisory authorities shall assess whether the submission of information would be overly burdensome in relation to the nature, scale and complexity of the risks of the undertaking, taking into account, at least:

(a) the volume of premiums, technical provisions and assets of the undertaking;

(b) the volatility of the claims and benefits covered by the undertaking;

(c) the market risks that the investments of the undertaking give rise to;

(d) the level of risk concentrations;

(e) the total number of classes of life and non-life insurance for which authorisation is granted;

(f) possible effects of the management of the assets of the undertaking on financial stability;

(g) the systems and structures of the undertaking to provide information for supervisory purposes and the written policy referred to in paragraph 5;

(h) the appropriateness of the system of governance of the undertaking;

(i) the level of own funds covering the Solvency Capital Requirement and the Minimum Capital Requirement;

(j) whether the undertaking is a captive insurance or reinsurance undertaking only covering risks associated with the industrial or commercial group to which it belongs.

9. The Commission shall adopt delegated acts in accordance with Article 301a specifying the information referred to in paragraphs 1 to 4 of this Article and the deadlines for the submission of that information, with a view to ensuring to the appropriate extent convergence of supervisory reporting.

10. In order to ensure uniform conditions of application of this Article, EIOPA shall develop draft implementing technical standards on regular supervisory reporting with regard to the templates for the submission of information to the supervisory authorities referred to in paragraphs 1 and 2.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

11. In order to enhance a coherent and consistent application of paragraphs 6 and 7, EIOPA shall issue guidelines in accordance with Article 16 of Regulation (EU) No 1094/2010 to further specify the methods to be used when determining the market shares referred to in the third subparagraph of paragraphs 6 and 7.';

(8) Article 37 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (b) is replaced by the following:

'(b) the supervisory authority concludes that the risk profile of the insurance or reinsurance undertaking deviates significantly from the assumptions underlying the Solvency Capital Requirement, as calculated using an internal model or partial internal model in accordance with Chapter VI, Section 4, Subsection 3, because certain quantifiable risks are captured insufficiently and the adaptation of the model to better reflect the given risk profile has failed within an appropriate timeframe;';

(ii) the following point is added:

'(d) the insurance or reinsurance undertaking applies the matching adjustment referred to in Article 77b, the volatility adjustment referred to in Article 77d or the transitional measures referred to in Articles 308c and 308d and the supervisory authority concludes that the risk profile of that undertaking deviates significantly from the assumptions underlying those adjustments and transitional measures.';

(b) paragraph 2 is replaced by the following:

'2. In the circumstances set out in points (a) and (b) of paragraph 1, the capital add-on shall be calculated in such a way as to ensure that the undertaking complies with Article 101(3).

In the circumstances set out in paragraph 1(c) the capital add-on shall be proportionate to the material risks arising from the deficiencies which gave rise to the decision of the supervisory authority to set the add-on.

In the circumstances set out in paragraph 1(d), the capital add-on shall be proportionate to the material risks arising from the deviation referred to in that paragraph.';

(c) paragraph 6 is replaced by the following:

'6. The Commission shall adopt delegated acts in accordance with Article 301a laying down further specifications for the circumstances under which a capital add-on may be imposed.

7. The Commission shall adopt delegated acts in accordance with Article 301a laying down further specifications for the methodologies for the calculation of capital add-ons.

8. In order to ensure uniform conditions of application in relation to this Article, EIOPA shall develop draft implementing technical standards on the procedures for decisions to set, calculate and remove capital add-ons.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 September 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(9) in Article 38(2), the following subparagraphs are added:

'Where a supervisory authority has informed the appropriate authority of the Member State of the service provider that it intends to carry out an on-site inspection in accordance with this paragraph, or where it carries out an on-site inspection in accordance with the first subparagraph where that supervisory authority is unable in practice to exercise its right to carry out that on-site inspection, the supervisory authority may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.

In accordance with Article 21 of Regulation (EU) No 1094/2010, EIOPA shall be entitled to participate in on-site examination where they are carried out jointly by two or more supervisory authorities.';

(10) Article 44 is amended as follows:

(a) in paragraph 2, the following subparagraph is added:

'Where insurance or reinsurance undertakings apply the matching adjustment referred to in Article 77b or the volatility adjustment referred to in Article 77d, they shall set up a liquidity plan projecting the incoming and outgoing cash flows in relation to the assets and liabilities subject to those adjustments.';

(b) the following paragraph is inserted:

'2a. As regards asset-liability management, insurance and reinsurance undertakings shall regularly assess:

(a) the sensitivity of their technical provisions and eligible own funds to the assumptions underlying the extrapolation of the relevant risk-free interest rate term structure referred to in Article 77a;

(b) where the matching adjustment referred to in Article 77b is applied:

(i) the sensitivity of their technical provisions and eligible own funds to the assumptions underlying the calculation of the matching adjustment, including the calculation of the fundamental spread referred to in Article 77c(1)(b), and the possible effect of a forced sale of assets on their eligible own funds;

(ii) the sensitivity of their technical provisions and eligible own funds to changes in the composition of the assigned portfolio of assets;

(iii) the impact of a reduction of the matching adjustment to zero;

(c) where the volatility adjustment referred to in Article 77d is applied:

(i) the sensitivity of their technical provisions and eligible own funds to the assumptions underlying the calculation of the volatility adjustment and the possible effect of a forced sale of assets on their eligible own funds;

(ii) the impact of a reduction of the volatility adjustment to zero.

Insurance and reinsurance undertakings shall submit the assessments referred to in points (a), (b) and (c) of the first subparagraph annually to the supervisory authority as part of the information reported under Article 35. Where the reduction of the matching adjustment or the volatility adjustment to zero would result in non-compliance with the Solvency Capital Requirement, the undertaking shall also submit an analysis of the measures it could apply in such a situation to re-establish the level of eligible own funds covering the Solvency Capital Requirement or to reduce its risk profile to restore compliance with the Solvency Capital Requirement.

Where the volatility adjustment referred to in Article 77d is applied, the written policy on risk management referred to in Article 41(3) shall comprise a policy on the criteria for the application of the volatility adjustment.';

(c) the following paragraph is inserted:

'4a. In order to avoid overreliance on external credit assessment institutions when they use external credit rating assessment in the calculation of technical provisions and the Solvency Capital Requirement, insurance and reinsurance undertakings shall assess the appropriateness of those external credit assessments as part of their risk management by using additional assessments wherever practicably possible in order to avoid any automatic dependence on external assessments.

In order to ensure uniform conditions of application of this paragraph, EIOPA shall develop draft implementing technical standards on the procedures for assessing external credit assessments.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the second subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(11) in Article 45, the following paragraph is inserted:

'2a. Where the insurance or reinsurance undertaking applies the matching adjustment referred to in Article 77b, the volatility adjustment referred to in Article 77d or the transitional measures referred to in Article 308c and 308d, they shall perform the assessment of compliance with the capital requirements referred to in paragraph 1(b) with and without taking into account those adjustments and transitional measures.';

(12) Article 50 is replaced by the following:

'Article 50

Delegated acts and regulatory technical standards

1. The Commission shall adopt delegated acts in accordance with Article 301a to further specify the following:

(a) the elements of the systems referred to in Articles 41, 44, 46 and 47, and in particular the areas to be covered by the asset–liability management and investment policy, as referred to in Article 44(2), of insurance and reinsurance undertakings;

(b) the functions referred to in Articles 44, 46, 47 and 48.

2. In order to ensure consistent harmonisation in relation to this Section, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to further specify the following:

(a) the requirements set out in Article 42 and the functions subject thereto;

(b) the conditions for outsourcing, in particular to service providers located in third countries.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

3. In order to ensure consistent harmonisation in relation to the assessment referred to in Article 45(1)(a), EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to further specify the elements of that assessment.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.';

(13) Article 51 is amended as follows:

(a) the following paragraph is inserted:

'1a. Where the matching adjustment referred to in Article 77b is applied, the description referred to in paragraph 1(d) shall include a description of the matching adjustment and of the portfolio of obligations and assigned assets to which the matching adjustment is applied, as well as a quantification of the impact of a change to zero of the matching adjustment on the undertaking's financial position.

The description referred to in paragraph 1(d) shall also include a statement on whether the volatility adjustment referred to in Article 77d is used by the undertaking and a quantification of the impact of a change to zero of the volatility adjustment on the undertaking's financial position.';

(b) in paragraph 2, the third subparagraph is replaced by the following:

'However, and without prejudice to any disclosure that is mandatory under any other legal or regulatory requirements, Member States may provide that, although the total Solvency Capital Requirement referred to in paragraph 1(e)(ii) is disclosed, the capital add-on or the impact of the specific parameters the insurance or reinsurance undertaking is required to use in accordance with Article 110 need not be separately disclosed during a transitional period ending no later than 31 December 2020.';

(14) Article 52 is replaced by the following:

'Article 52

Information for and reports by the European Insurance and Occupational Pensions Authority

1. Without prejudice to Article 35 of Regulation (EU) No 1094/2010, Member States shall require the supervisory authorities to provide the following information to EIOPA on an annual basis:

(a) the average capital add-on per undertaking and the distribution of capital add-ons imposed by the supervisory authority during the previous year, measured as a percentage of the Solvency Capital Requirement, shown separately for:

(i) insurance and reinsurance undertakings;

(ii) life insurance undertakings;

(iii) non-life insurance undertakings;

(iv) insurance undertakings pursuing both life and non-life activities;

(v) reinsurance undertakings;

(b) for each of the disclosures set out in point (a) of this paragraph, the proportion of capital add-ons imposed under Article 37(1)(a), (b) and (c) respectively;

(c) the number of insurance and reinsurance undertakings benefiting from the limitation from regular supervisory reporting and the number of insurance and reinsurance undertakings benefiting from the exemption of reporting on an item-by-item basis referred to in Article 35(6) and (7), together with their volume of capital requirements, premiums, technical provisions and assets, respectively measured as percentages of the total volume of capital requirements, premiums, technical provisions and assets of the insurance and reinsurance undertakings of the Member State;

(d) the number of groups benefiting from the limitation from regular supervisory reporting and the number of groups benefiting from the exemption of reporting on an item-by-item basis referred to in Article 254(2) together with their volume of capital requirements, premiums, technical provisions and assets, respectively measured as percentages of the total volume of capital requirements, premiums, technical provisions and assets of all the groups.

2. EIOPA shall publicly disclose, on an annual basis, the following information:

(a) for all Member States together, the total distribution of capital add-ons, measured as a percentage of the Solvency Capital Requirement, for each of the following:

(i) insurance and reinsurance undertakings;

(ii) life insurance undertakings;

(iii) non-life insurance undertakings;

(iv) insurance undertakings pursuing both life and non-life activities;

(v) reinsurance undertakings;

(b) for each Member State separately, the distribution of capital add-ons, measured as a percentage of the Solvency Capital Requirement, covering all insurance and reinsurance undertakings in that Member State;

(c) for each of the disclosures referred to in points (a) and (b) of this paragraph, the proportion of capital add-ons imposed under Article 37(1)(a), (b) and (c) respectively;

(d) for all Member States collectively, the total number of insurance and reinsurance undertakings and groups benefiting from the limitation from regular supervisory reporting and the total number of insurance and reinsurance undertakings and groups benefiting from the exemption of reporting on an item-by-item basis referred to in Article 35(6) and (7) and Article 254(2), together with their volume of capital requirements, premiums, technical provisions and assets, respectively measured as percentages of the total volume of capital requirements, premiums, technical provisions and assets of all insurance and reinsurance undertakings and groups;

(e) for each Member State separately, the number of insurance and reinsurance undertakings and groups benefiting from the limitation from regular supervisory reporting and the number of insurance and reinsurance undertakings and groups benefiting from the exemption of reporting on an item-by-item basis referred to in Article 35(6) and (7) and Article 254(2), together with their volume of capital requirements, premiums, technical provisions and assets, respectively measured as percentages of the total volume of premiums, technical provisions and assets of the insurance and reinsurance undertakings and groups of the Member State.

3. EIOPA shall provide the information referred to in paragraph 2 to the European Parliament, the Council and the Commission, together with a report outlining the degree of supervisory convergence in the use of capital add-ons between supervisory authorities in the different Member States.';

(15) Article 56 is replaced by the following:

'Article 56

Solvency and financial condition report: delegated acts and implementing technical standards

The Commission shall adopt delegated acts in accordance with Article 301a further specifying the information which must be disclosed and the deadlines for the annual disclosure of the information in accordance with Section 3.

In order to ensure uniform conditions of application of this Section, EIOPA shall develop draft implementing technical standards on the procedures, formats and templates.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the second paragraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(16) in Article 58, paragraph 8 is replaced by the following:

'8. In order to ensure consistent harmonisation in relation to this Section, EIOPA may develop draft regulatory technical standards to establish an exhaustive list of information, referred to in Article 59(4), to be included by proposed acquirers in their notification, without prejudice to Article 58(2).

In order to ensure consistent harmonisation in relation to this Section and to take account of future developments, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify the adjustments of the criteria set out in Article 59(1).

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first and second subparagraphs in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

9. In order to ensure uniform conditions of application of this Directive, EIOPA may develop draft implementing technical standards on the procedures, forms and templates for the consultation process between the relevant supervisory authorities as referred to in Article 60.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(17) the following article is inserted:

'Article 65a

Cooperation with EIOPA

Member States shall ensure that the supervisory authorities cooperate with EIOPA for the purposes of this Directive in accordance with Regulation (EU) No 1094/2010.

Member States shall ensure that the supervisory authorities provide EIOPA, without delay, with all the information necessary to carry out its duties in accordance with Regulation (EU) No 1094/2010.';

(18) the following article is inserted:

'Article 67a

European Parliament powers of investigation

Articles 64 and 67 shall be without prejudice to the powers of investigation conferred on the European Parliament by Article 226 of the Treaty on the Functioning of the European Union (TFEU).';

(19) in Article 69, the second paragraph is replaced by the following:

'Such disclosure shall be made only where necessary for reasons of prudential control. Member States shall, however, provide that information received under Article 65 and Article 68(1), and information obtained by means of on-site verification referred to in Article 33, may be disclosed only with the express consent of the supervisory authority from which the information originated or the supervisory authority of the Member State in which the on-site verification was carried out.';

(20) Article 70 is replaced by the following:

'Article 70

Transmission of information to central banks, monetary authorities, payment systems overseers and the European Systemic Risk Board

1. Without prejudice to Articles 64 to 69, a supervisory authority may transmit information intended for the performance of their tasks to the following:

(a) central banks of the European System of Central Banks (ESCB), including the European Central Bank (ECB) and other bodies with a similar function in their capacity as monetary authorities where this information is relevant to their respective statutory tasks, including the conduct of monetary policy and related liquidity provision, oversight of payments, clearing and securities settlement systems and safeguarding the stability of the financial system;

(b) where appropriate, other national public authorities responsible for overseeing payment systems; and

(c) the European Systemic Risk Board (ESRB), established by Regulation (EU) No 1092/2010 of the European Parliament and of the Council (*), where that information is relevant to carrying out its tasks.

2. In an emergency situation, including an emergency situation as referred to in Article 18 of Regulation (EU) No 1094/2010, Member States shall allow the supervisory authorities to communicate, without delay, information to the central banks of the ESCB, including the ECB, where that information is relevant to their statutory tasks including the conduct of monetary policy and related liquidity provision, oversight of payments, clearing and securities settlement systems and safeguarding the stability of the financial system, and to the ESRB, where such information is relevant to its tasks.

3. Such authorities or bodies may also communicate to the supervisory authorities such information as they may need for the purposes of Article 67. Information received in this context shall be subject to the provisions on professional secrecy laid down in this Section.

(*) Regulation (EU) No 1092/2010 of the European Parliament and of the Council of 24 November 2010 on European Union macro-prudential oversight of the financial system and establishing a European Systemic Risk Board (OJ L 331, 15.12.2010, p. 1).';

(21) Article 71 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. Member States shall ensure that in the exercise of their duties supervisory authorities have regard to the convergence in respect of supervisory tools and supervisory practices in the application of the laws, regulations and administrative requirements adopted pursuant to this Directive. For that purpose, Member States shall ensure that:

(a) the supervisory authorities participate in the activities of EIOPA;

(b) the supervisory authorities make every effort to comply with the guidelines and recommendations issued by EIOPA in accordance with Article 16 of Regulation (EU) No 1094/2010 and state reasons if they do not do so;

(c) national mandates conferred on the supervisory authorities do not inhibit the performance of their duties as members of EIOPA or under this Directive.';

(b) paragraph 3 is deleted;

(22) in Article 75, paragraph 2 is replaced by the following:

'2. The Commission shall adopt delegated acts in accordance with Article 301a to lay down the methods and assumptions to be used in the valuation of assets and liabilities as laid down in paragraph 1.

3. In order to ensure consistent harmonisation in relation to valuation of assets and liabilities, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify:

(a) to the extent that the delegated acts referred to in paragraph 2 require the use of international accounting standards as adopted by the Commission in accordance with Regulation (EC) No 1606/2002, the consistency of those accounting standards with the valuation approach of assets and liabilities as laid down in paragraphs 1 and 2;

(b) the methods and assumptions to be used where quoted market prices are either not available or where international accounting standards as adopted by the Commission in accordance with Regulation (EC) No 1606/2002 are either temporarily or permanently inconsistent with the valuation approach of assets and liabilities as laid down in paragraphs 1 and 2;

(c) the methods and assumptions to be used in the valuation of assets and liabilities as laid down in paragraph 1, where the delegated acts referred to in paragraph 2 allow for the use of alternative valuation methods.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.';

(23) the following articles are inserted:

'Article 77a

Extrapolation of the relevant risk-free interest rate term structure

The determination of the relevant risk-free interest rate term structure referred to in Article 77(2) shall make use of, and be consistent with, information derived from relevant financial instruments. That determination shall take into account relevant financial instruments of those maturities where the markets for those financial instruments as well as for bonds are deep, liquid and transparent. For maturities where the markets for the relevant financial instruments or for bonds are no longer deep, liquid and transparent, the relevant risk-free interest rate term structure shall be extrapolated.

The extrapolated part of the relevant risk-free interest rate term structure shall be based on forward rates converging smoothly from one or a set of forward rates in relation to the longest maturities for which the relevant financial instrument and the bonds can be observed in a deep, liquid and transparent market to an ultimate forward rate.

Article 77b

Matching adjustment to the relevant risk-free interest rate term structure

1. Insurance and reinsurance undertakings may apply a matching adjustment to the relevant risk-free interest rate term structure to calculate the best estimate of a portfolio of life insurance or reinsurance obligations, including annuities stemming from non-life insurance or reinsurance contracts subject to prior approval by the supervisory authorities where the following conditions are met:

(a) the insurance or reinsurance undertaking has assigned a portfolio of assets, consisting of bonds and other assets with similar cash-flow characteristics, to cover the best estimate of the portfolio of insurance or reinsurance obligations and maintains that assignment over the lifetime of the obligations, except for the purpose of maintaining the replication of expected cash flows between assets and liabilities where the cash flows have materially changed;

(b) the portfolio of insurance or reinsurance obligations to which the matching adjustment is applied and the assigned portfolio of assets are identified, organised and managed separately from other activities of the undertakings, and the assigned portfolio of assets cannot be used to cover losses arising from other activities of the undertakings;

(c) the expected cash flows of the assigned portfolio of assets replicate each of the expected cash flows of the portfolio of insurance or reinsurance obligations in the same currency and any mismatch does not give rise to risks which are material in relation to the risks inherent in the insurance or reinsurance business to which the matching adjustment is applied;

(d) the contracts underlying the portfolio of insurance or reinsurance obligations do not give rise to future premium payments;

(e) the only underwriting risks connected to the portfolio of insurance or reinsurance obligations are longevity risk, expense risk, revision risk and mortality risk;

(f) where the underwriting risk connected to the portfolio of insurance or reinsurance obligations includes mortality risk, the best estimate of the portfolio of insurance or reinsurance obligations does not increase by more than 5 % under a mortality risk stress that is calibrated in accordance with Article 101(2) to (5);

(g) the contracts underlying the portfolio of insurance or reinsurance obligations include no options for the policy holder or only a surrender option where the surrender value does not exceed the value of the assets, valued in accordance with Article 75, covering the insurance or reinsurance obligations at the time the surrender option is exercised;

(h) the cash flows of the assigned portfolio of assets are fixed and cannot be changed by the issuers of the assets or any third parties;

(i) the insurance or reinsurance obligations of an insurance or reinsurance contract are not split into different parts when composing the portfolio of insurance or reinsurance obligations for the purpose of this paragraph.

Notwithstanding point (h) of the first subparagraph, insurance or reinsurance undertakings may use assets where the cash flows are fixed except for a dependence on inflation, provided that those assets replicate the cash flows of the portfolio of insurance or reinsurance obligations that depend on inflation.

In the event that issuers or third parties have the right to change the cash flows of an asset in such a manner that the investor receives sufficient compensation to allow it to obtain the same cash flows by re-investing in assets of an equivalent or better credit quality, the right to change the cash flows shall not disqualify the asset for admissibility to the assigned portfolio in accordance with point (h) of the first subparagraph.

2. Insurance or reinsurance undertakings that apply the matching adjustment to a portfolio of insurance or reinsurance obligations shall not revert back to an approach that does not include a matching adjustment. Where an insurance or reinsurance undertaking that applies the matching adjustment is no longer able to comply with the conditions set out in paragraph 1, it shall immediately inform the supervisory authority and take the necessary measures to restore compliance with those conditions. Where the undertaking is not able to restore compliance with those conditions within two months of the date of non-compliance, it shall cease to apply the matching adjustment to any of its insurance or reinsurance obligations and shall not apply the matching adjustment for a period of a further 24 months.

3. The matching adjustment shall not be applied with respect to insurance or reinsurance obligations where the relevant risk-free interest rate term structure to calculate the best estimate for those obligations includes a volatility adjustment under Article 77d or transitional measure on the risk-free interest rates under Article 308c.

Article 77c

Calculation of the matching adjustment

1. For each currency the matching adjustment referred to in Article 77b shall be calculated in accordance with the following principles:

(a) the matching adjustment must be equal to the difference of the following:

(i) the annual effective rate, calculated as the single discount rate that, where applied to the cash flows of the portfolio of insurance or reinsurance obligations, results in a value that is equal to the value in accordance with Article 75 of the portfolio of assigned assets;

(ii) the annual effective rate, calculated as the single discount rate that, where applied to the cash flows of the portfolio of insurance or reinsurance obligations, results in a value that is equal to the value of the best estimate of the portfolio of insurance or reinsurance obligations where the time value of money is taken into account using the basic risk-free interest rate term structure;

(b) the matching adjustment must not include the fundamental spread reflecting the risks retained by the insurance or reinsurance undertaking;

(c) notwithstanding point (a), the fundamental spread must be increased where necessary to ensure that the matching adjustment for assets with sub-investment grade credit quality does not exceed the matching adjustments for assets of investment grade credit quality and the same duration and asset class;

(d) the use of external credit assessments in the calculation of the matching adjustment must be in accordance with Article 111(1)(n).

2. For the purposes of paragraph 1(b), the fundamental spread shall be:

(a) equal to the sum of the following:

(i) the credit spread corresponding to the probability of default of the assets;

(ii) the credit spread corresponding to the expected loss resulting from downgrading of the assets;

(b) for exposures to Member States' central governments and central banks, no lower than 30 % of the long-term average of the spread over the risk-free interest rate of assets of the same duration, credit quality and asset class, as observed in financial markets;

(c) for assets other than exposures to Member States' central governments and central banks, no lower than 35 % of the long-term average of the spread over the risk-free interest rate of assets of the same duration, credit quality and asset class, as observed in financial markets.

The probability of default referred to in point (a)(i) of the first subparagraph shall be based on long-term default statistics that are relevant for the asset in relation to its duration, credit quality and asset class.

Where no reliable credit spread can be derived from the default statistics referred to in the second subparagraph, the fundamental spread shall be equal to the portion of the long-term average of the spread over the risk-free interest rate set out in points (b) and (c).

Article 77d

Volatility adjustment to the relevant risk-free interest rate term structure

1. Member States may require prior approval by supervisory authorities for insurance and reinsurance undertakings to apply a volatility adjustment to the relevant risk-free interest rate term structure to calculate the best estimate referred to in Article 77(2).

2. For each relevant currency, the volatility adjustment to the relevant risk-free interest rate term structure shall be based on the spread between the interest rate that could be earned from assets included in a reference portfolio for that currency and the rates of the relevant basic risk-free interest rate term structure for that currency.

The reference portfolio for a currency shall be representative for the assets which are denominated in that currency and which insurance and reinsurance undertakings are invested in to cover the best estimate for insurance and reinsurance obligations denominated in that currency.

3. The amount of the volatility adjustment to risk-free interest rates shall correspond to 65 % of the risk-corrected currency spread.

The risk-corrected currency spread shall be calculated as the difference between the spread referred to in paragraph 2 and the portion of that spread that is attributable to a realistic assessment of expected losses or unexpected credit or other risk of the assets.

The volatility adjustment shall apply only to the relevant risk-free interest rates of the term structure that are not derived by means of extrapolation in accordance with Article 77a. The extrapolation of the relevant risk-free interest rate term structure shall be based on those adjusted risk-free interest rates.

4. For each relevant country, the volatility adjustment to the risk-free interest rates referred to in paragraph 3 for the currency of that country shall, before application of the 65 % factor, be increased by the difference between the risk-corrected country spread and twice the risk-corrected currency spread, whenever that difference is positive and the risk-corrected country spread is higher than 100 basis points. The increased volatility adjustment shall be applied to the calculation of the best estimate for insurance and reinsurance obligations of products sold in the insurance market of that country. The risk-corrected country spread is calculated in the same way as the risk-corrected currency spread for the currency of that country, but based on a reference portfolio that is representative for the assets which insurance and reinsurance undertakings are invested in to cover the best estimate for insurance and reinsurance obligations of products sold in the insurance market of that country and denominated in the currency of that country.

5. The volatility adjustment shall not be applied with respect to insurance obligations where the relevant risk-free interest rate term structure to calculate the best estimate for those obligations includes a matching adjustment under Article 77b.

6. By way of derogation from Article 101, the Solvency Capital Requirement shall not cover the risk of loss of basic own funds resulting from changes of the volatility adjustment.

Article 77e

Technical information produced by the European Insurance and Occupational Pensions Authority

1. EIOPA shall lay down and publish for each relevant currency the following technical information at least on a quarterly basis:

(a) a relevant risk-free interest rate term structure to calculate the best estimate referred to in Article 77(2), without any matching adjustment or volatility adjustment;

(b) for each relevant duration, credit quality and asset class a fundamental spread for the calculation of the matching adjustment referred to in Article 77c(1)(b);

(c) for each relevant national insurance market a volatility adjustment to the relevant risk-free interest rate term structure referred to in Article 77d(1).

2. In order to ensure uniform conditions for the calculation of technical provisions and basic own funds, the Commission may adopt implementing acts which set out, for each relevant currency, the technical information referred to in paragraph 1. Those implementing acts shall make use of that information.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 301(2).

On duly justified imperative grounds of urgency relating to the availability of the relevant risk-free interest rate term structure, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 301(3).

3. Where the technical information referred to in paragraph 1 is adopted by the Commission in accordance with paragraph 2, insurance and reinsurance undertakings shall use that technical information in calculating the best estimate in accordance with Article 77, the matching adjustment in accordance with Article 77c, and the volatility adjustment in accordance with Article 77d.

With respect to currencies and national markets where the adjustment referred to in paragraph 1(c) is not set out in the implementing acts referred to in paragraph 2, no volatility adjustment shall be applied to the relevant risk-free interest rate term structure to calculate the best estimate.

Article 77f

Review of long-term guarantees measures and measures on equity risk

1. EIOPA shall, on an annual basis and until 1 January 2021, report to the European Parliament, the Council and the Commission about the impact of the application of Articles 77a to 77e and 106, Article 138(4) and Articles 304, 308c and 308d, including the delegated or implementing acts adopted pursuant thereto.

Supervisory authorities shall, on an annual basis during that period, provide EIOPA with the following information:

(a) the availability of long-term guarantees in insurance products in their national markets and the behaviour of insurance and reinsurance undertakings as long-term investors;

(b) the number of insurance and reinsurance undertakings applying the matching adjustment, the volatility adjustment, the extension of the recovery period in accordance with Article 138(4), the duration-based equity risk sub-module and the transitional measures set out in Articles 308c and 308d;

(c) the impact on the insurance and reinsurance undertakings' financial position of the matching adjustment, the volatility adjustment, the symmetric adjustment mechanism to the equity capital charge, the duration-based equity risk sub-module and the transitional measures set out in Articles 308c and 308d, at national level and in anonymised way for each undertaking;

(d) the effect of the matching adjustment, the volatility adjustment, the symmetric adjustment mechanism to the equity capital charge and the duration-based equity risk sub-module on the investment behaviour of insurance and reinsurance undertakings and whether they provide undue capital relief;

(e) the effect of any extension of the recovery period in accordance with Article 138(4) on the efforts of insurance and reinsurance undertakings to re-establish the level of eligible own funds covering the Solvency Capital Requirement or to reduce the risk profile in order to ensure compliance with the Solvency Capital Requirement;

(f) where insurance and reinsurance undertakings apply the transitional measures set out in Articles 308c and 308d, whether they comply with the phasing-in plans referred to in Article 308e and the prospects for a reduced dependency on these transitional measures, including measures that have been taken or are expected to be taken by the undertakings and supervisory authorities, taking into account the regulatory environment of the Member State concerned.

2. EIOPA, where appropriate after consulting the ESRB and conducting a public consultation, shall submit to the Commission an opinion on the assessment of the application of Articles 77a to 77e and 106, Article 138(4), and Articles 304, 308c and 308d, including the delegated or implementing acts adopted pursuant thereto. That assessment shall be made in relation to the availability of long-term guarantees in insurance products, the behaviour of insurance and reinsurance undertakings as long-term investors and, more generally, financial stability.

3. Based on the opinion submitted by EIOPA, referred to in paragraph 2, the Commission shall submit a report to the European Parliament and to the Council by 1 January 2021, or, where appropriate, earlier. The report shall focus, in particular, on the effects on:

(a) policy holder protection;

(b) the functioning and stability of European insurance markets;

(c) the internal market and in particular the competition and the level playing field in European insurance markets;

(d) the extent to which insurance and reinsurance undertakings continue to operate as long-term investors;

(e) the availability and pricing of annuity products;

(f) the availability and pricing of competing products;

(g) long-term investment strategies by insurance undertakings in relation to products to which Articles 77b and 77c are applied relative to those in relation to other long-term guarantees;

(h) consumer choice and consumer awareness of risk;

(i) the degree of diversification in the insurance business and asset portfolio of insurance and reinsurance undertakings;

(j) financial stability.

In addition, the report shall build on the supervisory experience relating to the application of Articles 77a to 77e and 106, Article 138(4) and Articles 304, 308c and 308d, including the delegated or implementing acts adopted pursuant thereto.

4. The Commission report shall be accompanied, if necessary, by legislative proposals.';

(24) Article 86 is replaced by the following:

'Article 86

Delegated acts and regulatory and implementing technical standards

1. The Commission shall adopt delegated acts in accordance with Article 301a laying down the following:

(a) actuarial and statistical methodologies to calculate the best estimate referred to in Article 77(2);

(b) the methodologies, principles and techniques for the determination of the relevant risk-free interest rate term structure to be used to calculate the best estimate referred to in Article 77(2);

(c) the circumstances in which technical provisions shall be calculated as a whole, or as a sum of a best estimate and a risk margin, and the methods to be used in the case where technical provisions are calculated as a whole, as referred to in Article 77(4);

(d) the methods and assumptions to be used in the calculation of the risk margin including the determination of the amount of eligible own funds necessary to support the insurance and reinsurance obligations and the calibration of the cost-of-capital rate, as referred to in Article 77(5);

(e) the lines of business on the basis of which insurance and reinsurance obligations are to be segmented in order to calculate technical provisions referred to in Article 80;

(f) the standards to be met with respect to ensuring the appropriateness, completeness and accuracy of the data used in the calculation of technical provisions, and the specific circumstances in which it would be appropriate to use approximations, including case-by-case approaches, to calculate the best estimate, as referred to in Article 82;

(g) specifications with respect to the requirements set out in Article 77b(1) including the methods, assumptions and standard parameters to be used when calculating the impact of the mortality risk stress referred to in Article 77b(1)(e);

(h) specifications with respect to the requirements set out in Article 77c including assumptions and methods to apply in the calculation of the matching adjustment and the fundamental spread;

(i) methods and assumptions for the calculation of the volatility adjustment referred to in Article 77d including a formula for the calculation of the spread referred to in paragraph 2 of that Article.

2. In order to ensure consistent harmonisation in relation to the methods for the calculation of technical provisions, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify:

(a) the methodologies to be used when calculating the counterparty default adjustment referred to in Article 81 designed to capture expected losses due to default of the counterparty;

(b) where necessary, simplified methods and techniques to calculate technical provisions, in order to ensure the actuarial and statistical methods referred to in points (a) and (d) are proportionate to the nature, scale and complexity of the risks supported by insurance and reinsurance undertakings including captive insurance and reinsurance undertakings.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

3. In order to ensure consistent conditions of application of Article 77b, EIOPA shall develop draft implementing technical standards on the procedures for the approval of the application of a matching adjustment referred to in Article 77b(1).

EIOPA shall submit those draft implementing technical standards to the Commission by 31 October 2014.

Power is conferred on the Commission to adopt those implementing technical standards in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(25) Article 92 is amended as follows:

(a) the title is replaced by the following:

'Delegated acts and regulatory and implementing technical standards';

(b) paragraph 1 is replaced by the following:

'1. In order to ensure consistent harmonisation in relation to the determination of own funds, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify the criteria for granting supervisory approval of ancillary own funds in accordance with Article 90.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

1a. The Commission shall adopt delegated acts in accordance with Article 301a specifying the treatment of participations, within the meaning of the third subparagraph of Article 212(2), in financial and credit institutions with respect to the determination of own funds.';

(c) the following paragraph is added:

'3. In order to ensure uniform conditions of application of Article 90, EIOPA shall develop draft implementing technical standards on the procedures for granting supervisory approval for the use of ancillary own funds.

EIOPA shall submit those draft implementing technical standards to the Commission by 31 October 2014.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(26) Article 97 is replaced by the following:

'Article 97

Delegated acts and regulatory technical standards

1. The Commission shall adopt delegated acts in accordance with Article 301a laying down a list of own-fund items, including those referred to in Article 96, deemed to fulfil the criteria, set out in Article 94, which contains for each own-fund item a precise description of the features which determined its classification.

2. In order to ensure consistent harmonisation in relation to classification of own funds, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify the methods to be used by supervisory authorities, when approving the assessment and classification of own-fund items which are not covered by the list referred to in paragraph 1.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

The Commission shall regularly review and, where appropriate, update the list referred to in paragraph 1 in light of market developments.';

(27) Article 99 is replaced by the following:

'Article 99

Delegated acts on the eligibility of own funds

The Commission shall adopt delegated acts in accordance with Article 301a laying down:

(a) the quantitative limits referred to in Article 98(1) and (2);

(b) the adjustments that should be made to reflect the lack of transferability of those own-fund items that can be used only to cover losses arising from a particular segment of liabilities or from particular risks (ring-fenced funds).';

(28) the following article is inserted:

'Article 109a

Harmonised technical inputs to standard formula

1. For the purposes of the calculation of the Solvency Capital Requirement in accordance with the standard formula, the ESAs through the Joint Committee shall develop draft implementing technical standards on the allocation of credit assessments of external credit assessment institutions (ECAIs) to an objective scale of credit quality steps applying the steps specified in accordance with Article 111(1)(n).

The ESAs' Joint Committee shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

2. In order to ensure uniform conditions of application of this Article and for the purposes of facilitating the calculation of the market risk module referred to in Article 105(5), facilitating the calculation of the counterparty default risk module referred to in Article 105(6), evaluating risk mitigation techniques referred to in Article 101(5), and calculating technical provisions, EIOPA shall develop draft implementing technical standards on:

(a) lists of regional governments and local authorities, exposures to whom are to be treated as exposures to the central government of the jurisdiction in which they are established, provided that there is no difference in risk between such exposures because of the specific revenue-raising powers of the former, and specific institutional arrangements exist, the effect of which is to reduce the risk of default;

(b) the equity index referred to in Article 106(2), in accordance with the detailed criteria established under Article 111(1)(c) and (o);

(c) the adjustments to be made for currencies pegged to the euro in the currency risk sub-module referred to in Article 105(5), in accordance with the detailed criteria for the adjustments for currencies pegged to the euro for the purpose of facilitating the calculation of the currency risk sub-module, as established under Article 111(1)(p).

EIOPA shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

3. EIOPA shall publish technical information including information concerning the symmetric adjustment referred to in Article 106 on at least a quarterly basis.

4. In order to ensure uniform conditions of application of this Article and for the purpose of facilitating the calculation of the health underwriting risk module referred to in Article 105(4), EIOPA shall develop draft implementing technical standards, taking into account the calculations provided by the supervisory authorities of the Member States concerned, on standard deviations in relation to specific national legislative measures of Member States which permit the sharing of claims payments in respect of health risk amongst insurance and reinsurance undertakings and which meet the criteria in paragraph 5 and any additional criteria established by delegated acts.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

5. The implementing technical standards referred to in paragraph 4 shall apply only to the national legislative measures of Member States which permit the sharing of claims payments in respect of health risk amongst insurance and reinsurance undertakings and which meet the following criteria:

(a) the mechanism for the sharing of claims is transparent and fully specified in advance of the annual period to which it applies;

(b) the mechanism for the sharing of claims, the number of insurance undertakings that participate in the health risk equalisation system (HRES) and the risk characteristics of the business subject to the HRES ensure that for each undertaking participating in the HRES the volatility of annual losses of the business subject to the HRES is significantly reduced by means of the HRES, both in relation to premium and to reserve risk;

(c) health insurance subject to the HRES is compulsory and serves as a partial or complete alternative to health cover provided by the statutory social security system;

(d) in the event of default of insurance undertakings participating in the HRES, one or more Member States' governments guarantee to meet the policy holder claims of the insurance business that is subject to the HRES in full.

The Commission shall adopt delegated acts in accordance with Article 301a which set out the additional criteria that the national legislative measures arrangements shall meet, and the methodology and the requirements for the calculation of the standard deviations referred to in paragraph 4 of this Article.';

(29) Article 111 is replaced by the following:

'*Article 111*

Delegated acts and regulatory and implementing technical standards concerning Articles 103 to 109

1. The Commission shall adopt delegated acts in accordance with Article 301a providing for the following:

(a) a standard formula in accordance with Articles 101 and 103 to 109;

(b) any sub-modules necessary or covering more precisely the risks which fall under the respective risk modules referred to in Article 104 as well as any subsequent updates;

(c) the methods, assumptions and standard parameters to be calibrated to the confidence level referred to in Article 101(3) and to be used when calculating each of the risk modules or sub-modules of the basic Solvency Capital Requirement laid down in Articles 104, 105 and 304, the symmetric adjustment mechanism and the appropriate period of time, expressed in the number of months, as referred to in Article 106, and the appropriate approach for integrating the method referred to in Article 304 in the Solvency Capital Requirement as calculated in accordance with the standard formula;

(d) the correlation parameters, including, where necessary, those set out in Annex IV, and the procedures for updating those parameters;

(e) where insurance and reinsurance undertakings use risk-mitigation techniques, the methods and assumptions to be used to assess the changes in the risk profile of the undertaking concerned and to adjust the calculation of the Solvency Capital Requirement;

(f) the qualitative criteria that the risk-mitigation techniques referred to in point (e) must fulfil in order to ensure that the risk has been effectively transferred to a third party;

(fa) the method and parameters to be used when assessing the capital requirement for counterparty default risk in the case of exposures to qualifying central counterparties, those parameters ensuring consistency with the treatment of such exposures in the case of credit institutions and financial institutions within the meaning of Article 4(1)(1) and (26) of Regulation (EU) No 575/2013;

(g) the methods and parameters to be used when assessing the capital requirement for operational risk set out in Article 107, including the percentage referred to in Article 107(3);

(h) the methods and adjustments to be used to reflect the reduced scope for risk diversification of insurance and reinsurance undertakings relating to ring-fenced funds;

(i) the method to be used when calculating the adjustment for the loss absorbing capacity of technical provisions or deferred taxes, as laid down in Article 108;

(j) the subset of standard parameters in the life, non-life and health underwriting risk modules that may be replaced by undertaking-specific parameters as set out in Article 104(7);

(k) the standardised methods to be used by the insurance or reinsurance undertaking to calculate the undertaking-specific parameters referred to in point (j), and any criteria with respect to the completeness, accuracy, and appropriateness of the data used that must be met before supervisory approval is given together with the procedure to be followed for such approval;

(l) the simplified calculations provided for specific sub-modules and risk modules, as well as the criteria that insurance and reinsurance undertakings, including captive insurance and reinsurance undertakings, shall be required to fulfil in order to be entitled to use each of those simplifications, as set out in Article 109;

(m) the approach to be used with respect to related undertakings within the meaning of Article 212 in the calculation of the Solvency Capital Requirement, in particular the calculation of the equity risk sub-module referred to in Article 105(5), taking into account the likely reduction in the volatility of the value of those related undertakings arising from the strategic nature of those investments and the influence exercised by the participating undertaking on those related undertakings;

(n) how to use external credit assessments from ECAIs in the calculation of the Solvency Capital Requirement in accordance with the standard formula and the allocation of external credit assessments to a scale of credit quality steps referred to in Article 109a(1) which shall be consistent with the use of external credit assessments from ECAIs in the calculation of the capital requirements for credit institutions as defined in Article 4(1)(1) of Regulation (EU) No 575/2013 and financial institutions as defined in Article 4(1)(26) thereof;

(o) the detailed criteria for the equity index referred to in Article 109a(2)(c);

(p) the detailed criteria for the adjustments for currencies pegged to the euro for the purpose of facilitating the calculation of the currency risk sub-module referred to in Article 109a(2)(d);

(q) the conditions for a categorisation of regional governments and local authorities referred to in Article 109a(2)(a).

2. In order to ensure uniform conditions of application of this Article, EIOPA shall develop draft implementing technical standards on the procedures for supervisory approval of undertaking-specific parameters referred to in point (k) of paragraph 1.

EIOPA shall submit those draft implementing technical standards to the Commission by 31 October 2014.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

3. By 31 December 2020, the Commission shall make an assessment of the appropriateness of the methods, assumptions and standard parameters used when calculating the Solvency Capital Requirement standard formula. It shall in particular take into account the performance of any asset class and financial instruments, the behaviour of investors in those assets and financial instruments as well as developments in international standard setting in financial services. The review of certain asset classes may be prioritised. The Commission shall present a report to the European Parliament and to the Council, accompanied, where appropriate, by proposals for the amendment of this Directive, or of delegated or implementing acts adopted pursuant hereto.

4. In order to ensure consistent harmonisation in relation to the Solvency Capital Requirement, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify quantitative limits and asset eligibility criteria where those risks are not adequately covered by a sub-module.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

Those regulatory technical standards shall apply to assets covering technical provisions, excluding assets held in respect of life insurance contracts where the investment risk is borne by the policy holders. They shall be reviewed by the Commission in the light of developments in the standard formula and financial markets.';

(30) Article 114 is replaced by the following:

'Article 114

Delegated acts and implementing technical standards concerning the Solvency Capital Requirement internal models

1. The Commission shall adopt delegated acts in accordance with Article 301a setting out the following:

(a) the adaptations to be made to the standards set out in Articles 120 to 125 in light of the limited scope of the application of the partial internal model;

(b) the manner in which a partial internal model is to be fully integrated into the Solvency Capital Requirement standard formula referred to in Article 113(1)(c) and the requirements for the use of alternative integration techniques.

2. In order to ensure uniform conditions of application of this Article, EIOPA shall develop draft implementing technical standards on the procedures for:

(a) the approval of an internal model in accordance with Article 112; and

(b) the approval of major changes to an internal model and changes to the policy for changing an internal model referred to in Article 115.

EIOPA shall submit those draft implementing technical standards to the Commission by 31 October 2014.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(31) Article 127 is replaced by the following:

'Article 127

Delegated acts concerning Articles 120 to 126

The Commission shall adopt delegated acts in accordance with Article 301a with respect to Articles 120 to 126 to enhance the better assessment of the risk profile and management of the business of insurance and reinsurance undertakings regarding the use of internal models throughout the Union.';

(32) Article 129 is amended as follows:

(a) in paragraph 1(d), points (i), (ii) and (iii) are replaced by the following:

'(i) EUR 2 500 000 for non-life insurance undertakings, including captive insurance undertakings, save in the case where all or some of the risks included in one of the classes 10 to 15 listed in Part A of Annex I are covered, in which case it shall be no less than EUR 3 700 000;

(ii) EUR 3 700 000 for life insurance undertakings, including captive insurance undertakings;

(iii) EUR 3 600 000 for reinsurance undertakings, except in the case of captive reinsurance undertakings, in which case the Minimum Capital Requirement shall be not less than EUR 1 200 000;';

(b) in paragraph 3, the second subparagraph is replaced by the following:

'Member States shall allow their supervisory authorities, for a period ending no later than 31 December 2017, to require an insurance or reinsurance undertaking to apply the percentages referred to in the first subparagraph exclusively to the undertaking's Solvency Capital Requirement calculated in accordance with Chapter VI, Section 4, Subsection 2.';

(c) in paragraph 4, the following subparagraph is inserted after the first subparagraph:

'For the purposes of calculating the limits referred to in paragraph 3, undertakings shall not be required to calculate the Solvency Capital Requirement on a quarterly basis.';

(d) in paragraph 5, the first subparagraph is replaced by the following:

'5. The Commission shall submit to the European Parliament and the Council by 31 December 2020 a report on Member States' rules and supervisory authorities' practices adopted pursuant to paragraphs 1 to 4.';

(33) Article 130 is replaced by the following:

'Article 130

Delegated acts

The Commission shall adopt delegated acts in accordance with Article 301a specifying the calculation of the Minimum Capital Requirement, referred to in Articles 128 and 129.';

(34) in the first paragraph of Article 131, the dates '31 October 2012' and '31 October 2013' are replaced by the dates '31 December 2015' and '31 December 2016' respectively.

(35) Article 135 is replaced by the following:

'Article 135

Delegated acts and regulatory technical standards concerning qualitative requirements

1. The Commission may adopt delegated acts in accordance with Article 301a specifying qualitative requirements in the following areas:

(a) the identification, measurement, monitoring and managing of risks arising from investments in relation to the first subparagraph of Article 132(2);

(b) the identification, measurement, monitoring and managing of specific risks arising from investment in derivative instruments and assets referred to in the second subparagraph of Article 132(4) and the determination of the extent to which the use of such assets qualifies as risk reduction or efficient portfolio management as referred to in the third subparagraph of Article 132(4).

2. The Commission shall adopt delegated acts in accordance with Article 301a laying down:

(a) the requirements that need to be met by undertakings that repackage loans into tradable securities and other financial instruments (originators or sponsors) in order for an insurance or reinsurance undertaking to be allowed to invest in such securities or instruments issued after 1 January 2011, including requirements that ensure that the originator, sponsor or original lender retains, on an ongoing basis, a material net economic interest, which, in any event, shall not be less than 5 %;

(b) qualitative requirements that must be met by insurance or reinsurance undertakings that invest in such securities or instruments;

(c) the specifications for the circumstances under which a proportionate additional capital charge may be imposed when the requirements laid down under points (a) and (b) of this paragraph have been breached, without prejudice to Article 101(3).

3. In order to ensure consistent harmonisation in relation to paragraph 2(c), EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify the methodologies for the calculation of a proportionate additional capital charge referred to therein.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.';

(36) in Article 138, paragraph 4 is replaced by the following:

'4. In the event of exceptional adverse situations affecting insurance and reinsurance undertakings representing a significant share of the market or of the affected lines of business, as declared by EIOPA, and where appropriate after consulting the ESRB, the supervisory authority may extend, for affected undertakings, the period set out in the second subparagraph of paragraph 3 by a maximum period of seven years, taking into account all relevant factors including the average duration of the technical provisions.

Without prejudice to the powers of EIOPA under Article 18 of Regulation (EU) No 1094/2010, for the purposes of this paragraph EIOPA shall, following a request by the supervisory authority concerned, declare the existence of exceptional adverse situations. The supervisory authority concerned may make a request if insurance or reinsurance undertakings representing a significant share of the market or of the affected lines of business are unlikely to meet one of the requirements set out in paragraph 3. Exceptional adverse situations exist where the financial situation of insurance or reinsurance undertakings representing a significant share of the market or of the affected lines of business are seriously or adversely affected by one or more of the following conditions:

(a) a fall in financial markets which is unforeseen, sharp and steep;

(b) a persistent low interest rate environment;

(c) a high-impact catastrophic event.

EIOPA shall, in cooperation with the supervisory authority concerned, assess on a regular basis whether the conditions referred to in the second subparagraph still apply. EIOPA shall, in cooperation with the supervisory authority concerned, declare when an exceptional adverse situation has ceased to exist.

The insurance or reinsurance undertaking concerned shall, every three months, submit a progress report to its supervisory authority setting out the measures taken and the progress made to re-establish the level of eligible own funds covering the Solvency Capital Requirement or to reduce the risk profile to ensure compliance with the Solvency Capital Requirement.

The extension referred to in the first subparagraph shall be withdrawn where that progress report shows that there was no significant progress in achieving the re-establishment of the level of eligible own funds covering the Solvency Capital Requirement or the reduction of the risk profile to ensure compliance with the Solvency Capital Requirement between the date of the observation of non-compliance of the Solvency Capital Requirement and the date of the submission of the progress report.';

(37) Article 143 is replaced by the following:

'Article 143

Delegated acts and regulatory technical standards concerning Article 138(4)

1. The Commission shall adopt delegated acts in accordance with Article 301a supplementing the types of exceptional adverse situations and specifying the factors and criteria to be taken into account by EIOPA in declaring the existence of exceptional adverse situations and by supervisory authorities in determining the extension to recovery period in accordance with Article 138(4).

2. In order to ensure consistent harmonisation in relation to Article 138(2), Article 139(2) and Article 141, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify the recovery plan referred to in Article 138(2), and the finance scheme referred to in Article 139(2) and with respect to Article 141, taking due care to avoid pro-cyclical effects.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.';

(38) Article 149 is replaced by the following:

'Article 149

Changes in the nature of the risks or commitments

Any change which an insurance undertaking intends to make to the information referred to in Article 147 shall be subject to the procedure provided for in Articles 147 and 148.';

(39) Article 155 is amended as follows:

(a) in paragraph 3, the following subparagraph is inserted after the first subparagraph:

'In addition, the supervisory authority of the home or the host Member State may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.';

(b) paragraph 9 is replaced by the following:

'9. Member States shall inform the Commission and EIOPA of the number and types of cases which led to refusals under Articles 146 and 148 or in which measures have been taken under paragraphs 3 and 4 of this Article.';

(40) in Article 158(2), the following subparagraph is inserted after the first subparagraph:

'In addition, the supervisory authority of the home or the host Member State may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.';

(41) Article 159 is replaced by the following:

'Article 159

Statistical information on cross-border activities

Every insurance undertaking shall inform the competent supervisory authority of its home Member State, separately in respect of transactions carried out under the right of establishment and those carried out under the freedom to provide services, of the amount of the premiums, claims and commissions, without deduction of reinsurance, by Member State and as follows:

(a) for non-life insurance, by lines of business in accordance with the relevant delegated act;

(b) for life insurance, by lines of business in accordance with the relevant delegated act.

As regards class 10 in Part A of Annex I, excluding carrier's liability, the undertaking concerned shall also inform that supervisory authority of the frequency and average cost of claims.

The supervisory authority of the home Member State shall submit the information referred to in the first and second subparagraphs within reasonable time and in aggregate form to the supervisory authorities of each of the Member States concerned, upon their request.';

(42) Article 172 is replaced by the following:

'Article 172

Equivalence in relation to reinsurance undertakings

1. The Commission shall adopt delegated acts in accordance with Article 301a specifying the criteria for assessing whether the solvency regime of a third country that applies to reinsurance activities of undertakings with their head office in that third country is equivalent to that laid down in Title I.

2. If the criteria adopted in accordance with paragraph 1 have been fulfilled by a third country, the Commission may, in accordance with Article 301a, and assisted by EIOPA in accordance with Article 33(2) of Regulation (EU) No 1094/2010, adopt delegated acts determining that the solvency regime of that third country that applies to reinsurance activities of undertakings with the head office in that third country is equivalent to that laid down in Title I of this Directive.

Those delegated acts shall be regularly reviewed, to take into account any significant changes to the supervisory regime laid down in Title I, and to the supervisory regime in the third country.

EIOPA shall publish and keep up to date on its website a list of all third countries referred to in the first subparagraph.

3. Where, in accordance with paragraph 2, the solvency regime of a third country has been deemed to be equivalent to that laid down in this Directive, reinsurance contracts concluded with undertakings having their head office in that third country shall be treated in the same manner as reinsurance contracts concluded with undertakings authorised in accordance with this Directive.

4. By way of derogation from paragraph 2, and even if the criteria specified in accordance with paragraph 1 have not been fulfilled, the Commission may, for a limited period, in accordance with Article 301a, and assisted by EIOPA in accordance with Article 33(2) of Regulation (EU) No 1094/2010, adopt delegated acts determining that the solvency regime of a third country applied to reinsurance activities of undertakings with the head office in that third country is temporarily equivalent to that laid down in Title I, if that third country has complied with at least the following criteria:

(a) it has given a commitment to the Union to adopt and apply a solvency regime that is capable of being assessed equivalent in accordance with paragraph 2, before the end of that limited period and to engage in the equivalence assessment process;

(b) it has established a work programme to fulfil the commitment referred to in point (a);

(c) it has allocated sufficient resources to fulfil the commitment referred to in point (a);

(d) it has a solvency regime that is risk based and establishes quantitative and qualitative solvency requirements and requirements relating to supervisory reporting and transparency;

(e) it has entered into written arrangements to cooperate and exchange confidential supervisory information with EIOPA and supervisory authorities;

(f) it has an independent system of supervision; and

(g) it has established obligations on professional secrecy for all persons acting on behalf of its supervisory authorities, in particular on the exchange of information with EIOPA and supervisory authorities.

Any delegated acts on temporary equivalence shall take into account the reports by the Commission in accordance with Article 177(2). Those delegated acts shall be regularly reviewed on the basis of progress reports by the relevant third country, which are presented to and assessed by the Commission annually. EIOPA shall assist the Commission in the assessment of those progress reports.

EIOPA shall publish and keep up to date on its website a list of all third countries referred to in the first subparagraph.

The Commission may adopt delegated acts in accordance with Article 301a further specifying the conditions laid down in the first subparagraph.

5. The limited period referred to in the first subparagraph of paragraph 4 shall end on 31 December 2020 or on the date on which, in accordance with paragraph 2, the supervisory regime of that third country has been deemed to be equivalent to that laid down in Title I, whichever is the earlier.

That period may be extended by up to one year where necessary for EIOPA and the Commission to carry out the assessment of equivalence for the purposes of paragraph 2.

6. Reinsurance contracts concluded with undertakings having their head office in a third country, the supervisory regime of which has been deemed to be temporarily equivalent in accordance with paragraph 4, shall be accorded the same treatment as that set out in paragraph 3. Article 173 shall also apply to reinsurance undertakings having their head office in a third country, the supervisory regime of which has been deemed temporarily equivalent in accordance with paragraph 4.';

(43) Article 176 is replaced by the following:

'Article 176

Information from Member States to the Commission and EIOPA

The supervisory authorities of the Member States shall inform the Commission, EIOPA and the supervisory authorities of the other Member States of any authorisation of a direct or indirect subsidiary, one or more of whose parent undertakings are governed by the law of a third country.

That information shall also contain an indication of the structure of the group concerned.

Where an undertaking governed by the law of a third country acquires a holding in an insurance or reinsurance undertaking authorised in the Union which would turn that insurance or reinsurance undertaking into a subsidiary of that third country undertaking, the supervisory authorities of the home Member State shall inform the Commission, EIOPA and the supervisory authorities of the other Member States.';

(44) in Article 177, paragraph 1 is replaced by the following:

'1. Member States shall inform the Commission and EIOPA of any general difficulties encountered by their insurance or reinsurance undertakings in establishing themselves and operating in a third country or pursuing activities in a third country.';

(45) in Article 210, paragraph 2 is replaced by the following:

'2. The Commission may adopt delegated acts in accordance with Article 301a specifying the provisions referred to in paragraph 1 of this Article with respect to the monitoring, management and control of risks arising from finite reinsurance activities.';

(46) in Article 211, paragraphs 2 and 3 are replaced by the following:

'2. The Commission shall adopt delegated acts in accordance with Article 301a specifying the following criteria for supervisory approval:

(a) the scope of authorisation;

(b) mandatory conditions to be included in all contracts issued;

(c) fit and proper requirements, as referred to in Article 42, of the persons running the special purpose vehicle;

(d) fit and proper requirements for shareholders or members having a qualifying holding in the special purpose vehicle;

(e) sound administrative and accounting procedures, adequate internal control mechanisms and risk-management requirements;

(f) accounting, prudential and statistical information requirements;

(g) solvency requirements.

2a. In order to ensure uniform conditions of application of Article 211(1) and (2), EIOPA shall develop draft implementing technical standards on the procedures for granting supervisory approval to establish special purpose vehicles and on the formats and templates to be used for the purposes of point (f) of paragraph 2.

EIOPA shall submit those draft implementing technical standards to the Commission by 31 October 2014.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

2b. In order to ensure uniform conditions of application of Article 211(1) and (2), EIOPA may develop draft implementing technical standards on the procedures for the cooperation and exchange of information between supervisory authorities, where the special purpose vehicle which assumes risk from an insurance or reinsurance undertaking is established in a Member State which is not the Member State in which the insurance or reinsurance undertaking is authorised.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

3. Special purpose vehicles authorised before 31 December 2015 shall be subject to the law of the Member State that authorised the special purpose vehicle. However, any new activity commenced by such a special purpose vehicle after that date shall be subject to paragraphs 1, 2 and 2a.';

(47) in Article 212(1), point (e) is replaced by following:

'(e) "college of supervisors" means a permanent but flexible structure for the cooperation, coordination and facilitation of decision making concerning the supervision of a group;';

(48) Article 216 is amended as follows:

(a) in paragraph 1, the following subparagraphs are added:

'In such a case, the supervisory authority shall explain its decision to both the group supervisor and the ultimate parent undertaking at Union level. The group supervisor shall inform the college of supervisors in accordance with Article 248(1)(a).

Articles 218 to 258 shall apply *mutatis mutandis*, subject to paragraphs 2 to 6 of this Article.';

(b) in paragraph 4, the third subparagraph is replaced by the following:

'The supervisory authority shall explain such decisions to both the undertaking and the group supervisor. The group supervisor shall inform the college of supervisors in accordance with Article 248(1)(a).';

(c) paragraph 7 is replaced by the following:

'7. The Commission may adopt delegated acts in accordance with Article 301a specifying the circumstances under which the decision referred to in paragraph 1 of this Article can be made.';

(49) Article 217 is amended as follows:

(a) in paragraph 1, the following subparagraph is added:

'In such a case, the supervisory authorities shall explain their agreement to both the group supervisor and the ultimate parent undertaking at Union level. The group supervisor shall inform the college of supervisors in accordance with Article 248(1)(a).';

(b) paragraph 3 is replaced by the following:

'3. The Commission shall adopt delegated acts in accordance with Article 301a specifying the circumstances under which the decision referred to in paragraph 1 of this Article can be made.';

(50) Article 227 is replaced by the following:

'*Article 227*

Equivalence concerning related third-country insurance and re-insurance undertakings

1. When calculating the group solvency of an insurance or reinsurance undertaking which is a participating undertaking in a third-country insurance or reinsurance undertaking, in accordance with Article 233, the third-country insurance or reinsurance undertaking shall, solely for the purposes of that calculation, be treated as a related insurance or reinsurance undertaking.

However, where the third country in which that undertaking has its head office makes it subject to authorisation and imposes on it a solvency regime at least equivalent to that laid down in Title I, Chapter VI, Member States may provide that the calculation take into account, as regards that undertaking, the Solvency Capital Requirement and the own funds eligible to satisfy that requirement as laid down by the third country concerned.

2. Where no delegated act has been adopted in accordance with paragraph 4 or 5 of this Article, the verification of whether the third-country regime is at least equivalent shall be carried out by the group supervisor at the request of the participating undertaking or on its own initiative. EIOPA shall assist the group supervisor in accordance with Article 33(2) of Regulation (EU) No 1094/2010.

The group supervisor, assisted by EIOPA, shall consult the other supervisory authorities concerned before taking a decision on equivalence. That decision shall be taken in accordance with the criteria adopted in accordance with paragraph 3. The group supervisor shall not take any decision in relation to a third country that is contradicting any decision taken vis-à-vis that third country previously save where it is necessary to take into account significant changes to the supervisory regime laid down in Title I, Chapter VI and to the supervisory regime in the third country.

Where supervisory authorities disagree with the decision taken in accordance with subparagraph 2, they may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010 within three months after notification of the decision by the group supervisor. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.

3. The Commission may adopt delegated acts in accordance with Article 301a specifying the criteria for assessing whether the solvency regime of a third country is equivalent to that laid down in Title I, Chapter VI.

4. If the criteria adopted in accordance with paragraph 3 have been fulfilled by a third country, the Commission may, in accordance with Article 301a, and assisted by EIOPA in accordance with Article 33(2) of Regulation (EU) No 1094/2010, adopt delegated acts determining that the supervisory regime of that third country is equivalent to that laid down in Title I, Chapter VI.

Those delegated acts shall be regularly reviewed, to take into account any significant changes to the supervisory regime laid down in Title I, Chapter VI, and to the supervisory regime in the third country.

EIOPA shall publish and keep up to date on its website a list of all third countries referred to in the first subparagraph.

5. By way of derogation from paragraph 4, and even where the criteria specified in accordance with paragraph 3 have not been fulfilled, the Commission may, for the period referred to in paragraph 6, in accordance with Article 301a, and assisted by EIOPA in accordance with Article 33(2) of Regulation (EU) No 1094/2010, adopt delegated acts determining that the solvency regime of a third country applied to undertakings with the head office in that third country is provisionally equivalent to that laid down in Title I, Chapter VI, where:

(a) it can be shown that a solvency regime capable of being assessed equivalent in accordance with paragraph 4 is currently in place or may be adopted and applied by the third country;

(b) the third country has a solvency regime that is risk based and establishes quantitative and qualitative solvency requirements and requirements relating to supervisory reporting and transparency;

(c) the third country's law, in principle, allows cooperation, and exchange of confidential supervisory information, with EIOPA and supervisory authorities;

(d) the third country has an independent system of supervision; and

(e) the third country has established obligations on professional secrecy for all persons acting on behalf of its supervisory authorities.

EIOPA shall publish and keep up to date on its website a list of all third countries referred to in the first subparagraph.

6. The initial period of provisional equivalence referred to in paragraph 5 shall be 10 years, unless before the expiry of that period:

(a) that delegated act has been revoked; or

(b) a delegated act has been adopted in accordance with paragraph 4 to the effect that the supervisory regime of that third country has been deemed to be equivalent to that laid down in Title I, Chapter VI.

Provisional equivalence shall be subject to renewals for further periods of 10 years where the criteria referred to in paragraph 5 continue to be met. The Commission shall adopt any such delegated act in accordance with Article 301a and assisted by EIOPA in accordance with Article 33(2) of Regulation (EU) No 1094/2010.

Any delegated acts determining provisional equivalence shall take into account the reports by the Commission in accordance with Article 177(2). Such delegated acts shall be reviewed regularly by the Commission. EIOPA shall assist the Commission in the assessment of those decisions. The Commission shall inform the Parliament of any reviews taking place and shall report to the European Parliament on its conclusions.

7. Where, in accordance with paragraph 5, a delegated act determining that the supervisory regime of a third country is provisionally equivalent has been adopted, that third country shall be deemed to be equivalent of the purposes of the second subparagraph of paragraph 1.';

(51) Article 231 is replaced by the following:

'Article 231

Group internal model

1. In the case of an application for permission to calculate the consolidated group Solvency Capital Requirement, as well as the Solvency Capital Requirement of insurance and reinsurance undertakings in the group, on the basis of an internal model, submitted by an insurance or reinsurance undertaking and its related undertakings, or jointly by the related undertakings of an insurance holding company, the supervisory authorities concerned shall cooperate to decide whether or not to grant that permission and to determine the terms and conditions, if any, to which such permission is subject.

An application as referred to in the first subparagraph shall be submitted to the group supervisor.

The group supervisor shall inform the other members of the college of supervisors and forward the complete application to them, without delay.

2. The supervisory authorities concerned shall do everything within their power to reach a joint decision on the application within six months from the date of receipt of the complete application by the group supervisor.

3. If, within the six-month period referred to in paragraph 2, any of the supervisory authorities concerned has referred the matter to EIOPA in accordance with Article 19 of Regulation (EU) No 1094/2010, the group supervisor shall defer its decision and await any decision that EIOPA may take in accordance with Article 19(3) of that Regulation, and shall take its decision in conformity with EIOPA's decision. That decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned.

EIOPA shall take its decision within one month. The matter shall not be referred to EIOPA after the end of the six-month period or after a joint decision has been reached.

If, in accordance with Article 41(2) and (3) and Article 44(1)(3) of Regulation (EU) No 1094/2010, the decision proposed by the panel is rejected, the group supervisor shall take a final decision. That decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned. The six-month period shall be deemed the conciliation period within the meaning of Article 19(2) of that Regulation.

4. EIOPA may develop draft implementing technical standards to ensure uniform conditions of application of the joint decision process referred to in paragraph 2 with regard to the applications for permissions referred to in paragraph 1, with a view to facilitating joint decisions.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

5. Where the supervisory authorities concerned have reached a joint decision referred to in paragraph 2, the group supervisor shall provide the applicant with a document setting out the full reasons.

6. In the absence of the adoption of a joint decision within six months from the date of receipt of the complete application by the group, the group supervisor shall make its own decision on the application.

The group supervisor shall duly take into account any views and reservations of the other supervisory authorities concerned expressed during that six-month period.

The group supervisor shall provide the applicant and the other supervisory authorities concerned with a document setting out its fully reasoned decision.

That decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned.

7. Where any of the supervisory authorities concerned considers that the risk profile of an insurance or reinsurance undertaking under its supervision deviates significantly from the assumptions underlying the internal model approved at group level, and as long as that undertaking has not properly addressed the concerns of the supervisory authority, that authority may, in accordance with Article 37, impose a capital add-on to the Solvency Capital Requirement of that insurance or reinsurance undertaking resulting from the application of such internal model.

In exceptional circumstances, where such capital add-on would not be appropriate, the supervisory authority may require the undertaking concerned to calculate its Solvency Capital Requirement on the basis of the standard formula referred to in Title I, Chapter VI, Section 4, Subsections 1 and 2. In accordance with Article 37(1)(a) and (c), the supervisory authority may impose a capital add-on to the Solvency Capital Requirement of that insurance or reinsurance undertaking resulting from the application of the standard formula.

The supervisory authority shall explain any decision referred to in the first and second subparagraphs to both the insurance or reinsurance undertaking and the other members of the college of supervisors.

EIOPA may issue guidelines to ensure consistent and coherent application of this paragraph.';

(52) in the first paragraph of Article 232, the introductory part is replaced by the following:

'In determining whether the consolidated group Solvency Capital Requirement appropriately reflects the risk profile of the group, the group supervisor shall pay particular attention to any case where the circumstances referred to in Article 37(1)(a) to (d) may arise at group level, in particular where:';

(53) in Article 232, the third paragraph is replaced by the following:

'Article 37(1) to (5), together with the delegated acts and implementing technical standards taken in accordance with Article 37(6), (7) and (8) shall apply *mutatis mutandis*.';

(54) in Article 233(6), the third subparagraph is replaced by the following:

'Article 37(1) to (5), together with the delegated acts and implementing technical standards taken in accordance with Article 37(6), (7) and (8), shall apply *mutatis mutandis*.';

(55) Article 234 is replaced by the following:

'Article 234

Delegated acts concerning Articles 220 to 229 and 230 to 233

The Commission shall adopt delegated acts in accordance with Article 301a specifying the technical principles and methods set out in Articles 220 to 229 and the application of Articles 230 to 233, reflecting the economic nature of specific legal structures.';

(56) Article 237 is replaced by the following:

'Article 237

Subsidiaries of an insurance or reinsurance undertaking: decision on the application

1. In the case of applications for permission to be subject to the rules laid down in Articles 238 and 239, the supervisory authorities concerned shall work together within the college of supervisors, in full cooperation, to decide whether or not to grant the permission sought and to determine the other terms and conditions, if any, to which such permission should be subject.

An application as referred to in the first subparagraph shall be submitted only to the supervisory authority having authorised the subsidiary. That supervisory authority shall inform the other members of the college of supervisors and forward the complete application to them, without delay.

2. The supervisory authorities concerned shall do everything within their power to reach a joint decision on the application within three months from the date of receipt of the complete application by all supervisory authorities within the college of supervisors.

3. If, within the three-month period referred to in paragraph 2, any of the supervisory authorities concerned has referred the matter to EIOPA in accordance with Article 19 of Regulation (EU) No 1094/2010, the group supervisor shall defer its decision and await any decision that EIOPA may take in accordance with Article 19(3) of that Regulation, and shall take its decision in conformity with EIOPA's decision. That decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned.

EIOPA shall take its decision within one month. The matter shall not be referred to EIOPA after the end of the three-month period or after a joint decision has been reached.

If, in accordance with Article 41(2) and (3) and Article 44(1)(3) of Regulation (EU) No 1094/2010, the decision proposed by the panel is rejected, the group supervisor shall take a final decision. That decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned. The three-month period shall be deemed the conciliation period within the meaning of Article 19(2) of that Regulation.

4. EIOPA may develop draft implementing technical standards to ensure uniform conditions of application of the joint decision process referred to in paragraph 2 with regard to the applications for permissions referred to in paragraph 1, with a view to facilitating joint decisions.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

5. Where the supervisory authorities concerned have reached a joint decision referred to in paragraph 2, the supervisory authority having authorised the subsidiary shall provide the applicant with the decision stating the full reasons. The joint decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned.

6. In the absence of a joint decision of the supervisory authorities concerned within the three-month period set out in paragraph 2, the group supervisor shall take its own decision with regard to the application.

During that period the group supervisor shall duly consider the following:

(a) any views and reservations of the supervisory authorities concerned;

(b) any reservations of the other supervisory authorities within the college of supervisors.

The decision shall state the full reasons and shall contain an explanation of any significant deviation from the reservations of the other supervisory authorities concerned. The group supervisor shall provide the applicant and the other supervisory authorities concerned with a copy of the decision. The decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned.';

(57) in Article 238, paragraph 4 is replaced by the following:

'4. The college of supervisors shall do everything within its power to reach an agreement on the proposal of the supervisory authority having authorised the subsidiary or on other possible measures.

That agreement shall be recognised as determinative and shall be applied by the supervisory authorities concerned.';

(58) in Article 238, paragraph 5 is replaced by the following:

'5. Where the supervisory authority and the group supervisor disagree, either supervisor may, within one month from the proposal of the supervisory authority, refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred to it by that Article, and shall take its decision within one month of such referral. The one-month period shall be deemed the conciliation period within the meaning of Article 19(2) of that Regulation. The matter shall not be referred to EIOPA after the end of the one-month period referred to in this subparagraph or after an agreement has been reached within the college in accordance with paragraph 4 of this Article.

The supervisory authority having authorised that subsidiary shall defer its decision and await any decision that EIOPA may take in accordance with Article 19 of that Regulation, and shall take its decision in conformity with EIOPA's decision.

That decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned.

The decision shall state the full reasons on which it is based.

The decision shall be submitted to the subsidiary and to the college of supervisors.';

(59) in Article 239, the following paragraph is added:

'4. The supervisory authority or the group supervisor may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010 where they disagree regarding either of the following:

(a) on the approval of the recovery plan, including any extension of the recovery period, within the four-month period referred to in paragraph 1; or

(b) on the approval of the proposed measures, within the one-month period referred to in paragraph 2.

In those cases, EIOPA may act in accordance with the powers conferred to it by that Article, and shall take its decision within one month of such referral.

The matter shall not be referred to EIOPA:

(a) after the end of the four-month or the one-month period respectively referred to in the first subparagraph;

(b) after an agreement has been reached within the college in accordance with the second subparagraph of paragraph 1 or the second subparagraph of paragraph 2;

(c) in the case of emergency situations as referred to in paragraph 2.

The four-month or the one-month period respectively shall be deemed the conciliation period within the meaning of Article 19(2) of that Regulation.

The supervisory authority having authorised that subsidiary shall defer its decision and await any decision that EIOPA may take in accordance with Article 19(3) of that regulation, and shall take its final decision in conformity with EIOPA's decision. That decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned.

The decision shall state the full reasons on which it is based.

The decision shall be submitted to the subsidiary and to the college of supervisors.';

(60) Article 241 is replaced by the following:

'Article 241

Subsidiaries of an insurance or reinsurance undertaking: delegated acts

The Commission shall adopt delegated acts in accordance with Article 301a specifying:

(a) the criteria for assessing whether the conditions stated in Article 236 are satisfied;

(b) the criteria for assessing what should be considered an emergency situation under Article 239(2);

(c) the procedures to be followed by supervisory authorities when exchanging information, exercising their rights and fulfilling their duties in accordance with Articles 237 to 240.';

(61) in Article 242, paragraph 1 is replaced by the following:

'1. By 31 December 2017, the Commission shall make an assessment of the application of Title III, in particular as regards the cooperation of supervisory authorities within, and functionality of, the college of supervisors and the supervisory practices concerning setting the capital add-ons, and shall present a report to the European Parliament and to the Council accompanied, where appropriate, by proposals for the amendment of this Directive.';

(62) in Article 242(2), the date '31 October 2015' is replaced by the date '31 December 2018';

(63) in Article 244, paragraph 4 is replaced by the following:

'4. The Commission shall adopt delegated acts in accordance with Article 301a as regards the definition of a significant risk concentration for the purposes of paragraphs 2 and 3 of this Article.

5. In order to ensure consistent harmonisation in relation to supervision of risk concentration, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify the identification of a significant risk concentration and the determination of appropriate thresholds for the purposes of paragraph 3.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

6. In order to ensure uniform conditions of application of this Article, EIOPA shall develop draft implementing technical standards on the forms and templates for reporting on such risk concentrations for the purposes of paragraph 2.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 September 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(64) in Article 245, paragraph 4 is replaced by the following:

'4. The Commission shall adopt delegated acts in accordance with Article 301a as regards the definition of a significant intra-group transaction for the purposes of paragraphs 2 and 3 of this Article.

5. In order to ensure consistent harmonisation in relation to supervision of intra-group transactions, EIOPA may develop draft regulatory technical standards to specify the identification of a significant intra-group transaction for the purposes of paragraph 3.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

6. In order to ensure uniform conditions of application of this Article, EIOPA may develop draft implementing technical standards on the procedures, forms and templates for the reporting on such intra-group transactions for the purposes of paragraph 2.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(65) in Article 247, paragraphs 3 to 7 are replaced by the following:

'3. In particular cases, the supervisory authorities concerned may, at the request of any of the other supervisory authorities, take a joint decision to derogate from the criteria set out in paragraph 2 where their application would be inappropriate, taking into account the structure of the group and the relative importance of the insurance and reinsurance undertakings' activities in different countries, and designate a different supervisory authority as group supervisor.

For that purpose, any of the supervisory authorities concerned may request that a discussion be opened on whether the criteria referred to in paragraph 2 are appropriate. Such a discussion shall not take place more often than annually.

The supervisory authorities concerned shall do everything within their power to reach a joint decision on the choice of the group supervisor within three months from the request for discussion. Before taking their decision, the supervisory authorities concerned shall give the group an opportunity to state its opinion.

The designated group supervisor shall submit the joint decision to the group stating the full reasons.

4. If, within the three-month period referred to in the third subparagraph of paragraph 3, any of the supervisory authorities concerned has referred the matter to EIOPA in accordance with Article 19 of Regulation (EU) No 1094/2010, the supervisory authorities concerned shall defer their joint decision and await any decision that EIOPA may take in accordance with Article 19(3) of that Regulation, and shall take their joint decision in conformity with EIOPA's decision. That joint decision shall be recognised as determinative and shall be applied by the supervisory authorities concerned. The three-month period shall be deemed the conciliation period within the meaning of Article 19(2) of that Regulation.

5. EIOPA shall take its decision within one month of a referral under paragraph 4. The matter shall not be referred to EIOPA after the end of the three-month period or after a joint decision has been reached. The designated group supervisor shall submit the joint decision to the group and to the college of supervisors stating the full reasons.

6. In the absence of a joint decision, the task of group supervisor shall be exercised by the supervisory authority identified in accordance with paragraph 2 of this Article.

7. EIOPA shall inform the European Parliament, the Council and the Commission of any major difficulties with the application of paragraphs 2, 3 and 6 on at least an annual basis.

In the event that any major difficulties arise from the application of the criteria set out in paragraphs 2 and 3 of this Article, the Commission shall adopt delegated acts in accordance with Article 301a further specifying those criteria.';

(66) Article 248 is amended as follows:

(a) in paragraph 2, the following subparagraph is added:

'Where the group supervisor fails to carry out the tasks referred to in paragraph 1 or where the members of the college of supervisors do not cooperate to the extent required in this paragraph, any of the supervisory authorities concerned may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.';

(b) in paragraph 3, the first subparagraph is replaced by the following:

'3. The membership of the college of supervisors shall include the group supervisor, the supervisory authorities of all the Member States in which the head offices of all subsidiary undertakings are situated, and EIOPA in accordance with Article 21 of Regulation (EU) No 1094/2010.';

(c) in paragraph 4, the second subparagraph is replaced by the following:

'Where diverging views concerning the coordination arrangements arise, any member of the college of supervisors may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred on it by that Article. The group supervisor shall take its final decision in conformity with EIOPA's decision. The group supervisor shall transmit the decision to the other supervisory authorities concerned.'

(d) in paragraph 5, the second paragraph is replaced by the following:

'Without prejudice to the rights and duties allocated by this Directive to the group supervisor and to other supervisory authorities, the coordination arrangements may entrust additional tasks to the group supervisor, the other supervisory authorities or EIOPA where this would result in the more efficient supervision of the group and would not impair the supervisory activities of the members of the college of supervisors in respect of their individual responsibilities.';

(e) paragraphs 6 and 7 are replaced by the following:

'6. EIOPA shall issue guidelines for the operational functioning of colleges of supervisors on the basis of comprehensive reviews of their work in order to assess the level of convergence between them. Such reviews shall be carried out at least every three years. Member States shall ensure that the group supervisor transmits to EIOPA the information on the functioning of the colleges of supervisors and on any difficulties encountered that are relevant for those reviews.

In order to ensure consistent harmonisation in relation to the coordination between supervisory authorities, EIOPA may develop draft regulatory technical standards to specify the operational functioning of colleges of supervisors based on the guidelines referred to in the first subparagraph.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the second subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

7. In order to ensure consistent harmonisation in relation to the coordination between supervisory authorities, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify the coordination of group supervision for the purposes of paragraphs 1 to 6.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

8. The Commission shall adopt delegated acts in accordance with Article 301a in regard to the definition of "significant branch".';

(67) Article 249 is amended as follows:

(a) in paragraph 1, the second subparagraph is replaced by the following:

'With the objective of ensuring that the supervisory authorities, including the group supervisor, have the same amount of relevant information available to them, without prejudice to their respective responsibilities, and irrespective of whether they are established in the same Member State, they shall provide one another with such information in order to allow and facilitate the exercise of the supervisory tasks of the other authorities under this Directive. In that regard, the supervisory authorities concerned and the group supervisor shall communicate to one another without delay all relevant information as soon as it becomes available, or exchange information on request. The information referred to in this subparagraph includes, but is not limited to, information about actions of the group and supervisory authorities, and information provided by the group.';

(b) the following paragraph is inserted:

'1a. Where a supervisory authority has not communicated relevant information or a request for cooperation, in particular to exchange relevant information, has been rejected or has not been acted upon within two weeks, the supervisory authorities may refer the matter to EIOPA.

Where the matter is referred to it, EIOPA may, without prejudice to Article 258 TFEU, act in accordance with the powers conferred on it by Article 19 of Regulation (EU) No 1094/2010.';

(c) paragraph 3 is replaced by the following:

'3. In order to ensure consistent harmonisation in relation to the coordination and exchange of information between supervisory authorities, EIOPA shall, subject to Article 301b, develop draft regulatory technical standards to specify:

(a) the items which are, on a systematic basis, to be gathered by the group supervisor and disseminated to other supervisory authorities concerned or to be transmitted to the group supervisor by the other supervisory authorities concerned;

(b) the items essential or relevant for supervision at group level with a view to enhancing convergence of supervisory reporting.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

4. In order to ensure uniform conditions of application in relation to the coordination and exchange of information between supervisory authorities, EIOPA shall develop draft implementing technical standards on the procedures and templates for the submission of information to the group supervisor as well as the procedure for the cooperation and the exchange of information between supervisory authorities as laid down in this Article.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 September 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(68) Article 250 is amended as follows:

'Article 250

Consultation between supervisory authorities

1. Without prejudice to Article 248, the supervisory authorities concerned shall, where a decision is of importance for the supervisory tasks of other supervisory authorities, prior to that decision, consult each other in the college of supervisors with regard to the following:

(a) changes in the shareholder structure, organisational or management structure of insurance and reinsurance undertakings in a group, which require the approval or authorisation of supervisory authorities;

(b) the decision on the extension of the recovery period under Article 138(3) and (4);

(c) major sanctions or exceptional measures taken by supervisory authorities, including the imposition of a capital add-on to the Solvency Capital Requirement under Article 37 and the imposition of any limitation on the use of an internal model for the calculation of the Solvency Capital Requirement under Title I, Chapter VI, Section 4, Subsection 3.

For the purposes of points (b) and (c) of the first subparagraph, the group supervisor shall always be consulted.

In addition, the supervisory authorities concerned shall, where a decision is based on information received from other supervisory authorities, consult each other prior to that decision.

2. Without prejudice to Article 248, a supervisory authority may decide not to consult other supervisory authorities in cases of urgency or where such consultation could jeopardise the effectiveness of the decision. In that case, the supervisory authority shall, without delay, inform the other supervisory authorities concerned.';

(69) in Article 254(2), the first subparagraph is replaced by the following:

'2. Member States shall provide that their authorities responsible for exercising group supervision have access to any information relevant for the purpose of that supervision regardless of the nature of the undertaking concerned. Article 35(1) to (5) shall apply *mutatis mutandis*.

The group supervisor may limit regular supervisory reporting with a frequency shorter than one year at the level of the group where all insurance or reinsurance undertakings within the group benefit from the limitation in accordance with Article 35(6) taking into account the nature, scale and complexity of the risks inherent in the business of the group.

The group supervisor may exempt from reporting on an item-by-item basis at the level of the group where all insurance or reinsurance undertakings within the group benefit from the exemption in accordance with Article 35 (7), taking into account the nature, scale and complexity of the risks inherent in the business of the group and the objective of financial stability.';

(70) in Article 255(2), the following subparagraphs are added:

'Where the request to another supervisory authority to have a verification carried out in accordance with this paragraph has not been acted upon within two weeks, or where the supervisory authority is unable in practice to exercise its right to participate in accordance with the third subparagraph, the requesting authority may refer the matter to EIOPA and may request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.

In accordance with Article 21 of Regulation (EU) No 1094/2010, EIOPA shall be entitled to participate in on-site examinations where they are carried out jointly by two or more supervisory authorities.';

(71) Article 256 is amended as follows:

(a) paragraph 4 is replaced by the following:

'4. The Commission shall adopt delegated acts in accordance with Article 301a further specifying the information which must be disclosed and the deadlines for the annual disclosure of the information as regards the single solvency and financial condition report in accordance with paragraph 2 and the report on the solvency and financial condition report at the level of the group in accordance with paragraph 1.';

(b) the following paragraph is added:

'5. In order to ensure uniform conditions of application in relation to the single and group solvency and financial condition report, EIOPA shall develop draft implementing technical standards on the procedures and templates for, and the means of, disclosure of the single and group solvency and financial report as laid down in this Article.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the first subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.';

(72) the following article is inserted:

'Article 256a

Group structure

Member States shall require insurance and reinsurance undertakings, insurance holding companies and mixed financial holding companies to disclose publicly, at the level of the group, on an annual basis, the legal structure and the governance and organisational structure, including a description of all subsidiaries, material related undertakings and significant branches belonging to the group.';

(73) in Article 258, paragraph 3 is replaced by the following:

'3. The Commission may adopt delegated acts in accordance with Article 301a for the coordination of enforcement measures referred to in paragraphs 1 and 2 of this Article.';

(74) Article 259 is replaced by the following:

'Article 259

Reporting of EIOPA

1. EIOPA shall report to the European Parliament annually in accordance with Article 50 of Regulation (EU) No 1094/2010.

2. EIOPA shall report, inter alia, on all relevant and significant experiences of the supervisory activities and cooperation between supervisors in the framework of Title III, and, in particular:

(a) the process of the nomination of the group supervisor, the number of group supervisors and their geographical spread;

(b) the working of the college of supervisors, in particular the involvement and commitment of supervisory authorities where they are not the group supervisor.

3. EIOPA may, for the purposes of paragraph 1 of this Article, also report on the main lessons drawn from the reviews referred to in Article 248(6), where appropriate.';

(75) Article 260 is replaced by the following:

'Article 260

Parent undertakings outside the Union: verification of equivalence

1. In the case referred to in Article 213(2)(c), the supervisory authorities concerned shall verify whether the insurance and reinsurance undertakings, the parent undertaking of which has its head office outside the Union, are subject to supervision, by a third-country supervisory authority, which is equivalent to that provided for by this Title on the supervision at the level of the group of insurance and reinsurance undertakings referred to in Article 213(2)(a) and (b).

Where no delegated act has been adopted in accordance with paragraph 2, 3 or 5 of this Article, the verification shall be carried out by the supervisory authority, which would be the group supervisor if the criteria set out in Article 247(2) were to apply (the "acting group supervisor"), at the request of the parent undertaking or of any of the insurance and reinsurance undertakings authorised in the Union or on its own initiative. EIOPA shall assist the acting group supervisor in accordance with Article 33(2) of Regulation (EU) No 1094/2010.

In so doing, that acting group supervisor shall, assisted by EIOPA, consult the other supervisory authorities concerned, before taking a decision on equivalence. That decision shall be taken in accordance with the criteria adopted in accordance with paragraph 2. The acting group supervisor shall not take any decision in relation to a third country that is in opposition to any previous decision taken vis-à-vis that third country, save where it is necessary to take into account significant changes to the supervisory regime laid down in Title I and to the supervisory regime in the third country.

Where supervisory authorities disagree with the decision taken in accordance with the third subparagraph, they may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No 1094/2010 within three months after notification of the decision by the acting group supervisor. In that case, EIOPA may act in accordance with the powers conferred on it by that Article.

2. The Commission may adopt delegated acts in accordance with Article 301a specifying the criteria for assessing whether the prudential regime in a third country for the supervision of groups is equivalent to that laid down in this Title.

3. If the criteria adopted in accordance with paragraph 2 of this Article have been fulfilled by a third country, the Commission may, in accordance with Article 301a, and assisted by EIOPA in accordance with Article 33(2) of Regulation (EU) No 1094/2010, adopt delegated acts determining that the prudential regime of that third country is equivalent to that laid down in this Title.

Such a delegated act shall be regularly reviewed to take into account any changes to the prudential regime for the supervision of groups laid down in this Title, and to the prudential regime in the third country for the supervision of groups, and to any other change in regulation that may affect the decision on equivalence.

EIOPA shall publish and keep up to date on its website a list of all third countries referred to in the first subparagraph.

4. In the absence of a delegated act adopted by the Commission in accordance with paragraph 3 or 5 of this Article, Article 262 shall apply.

5. By way of derogation from paragraph 3, and even if the criteria specified in paragraph 2 have not been fulfilled, the Commission may, for a limited period and in accordance with Article 301a, and assisted by EIOPA in accordance with Article 33(2) of Regulation (EU) No 1094/2010, adopt delegated acts determining that the prudential regime of a third country applied to undertakings the parent undertaking of which has its head office outside the Union on 1 January 2014 is temporarily equivalent to that laid down in Title I, if that third country has complied with at least the following criteria:

(a) it has given a commitment to the Union to adopt and apply a prudential regime that is capable of being assessed equivalent in accordance with paragraph 3, before the end of that limited period and to engage in the equivalence assessment process;

(b) it has established a work programme to fulfil the commitment under point (a);

(c) it has allocated sufficient resources to fulfil the commitment under point (a);

(d) it has a prudential regime that is risk based and establishes quantitative and qualitative solvency requirements and requirements relating to supervisory reporting and transparency and to the supervision of groups;

(e) it has entered into written arrangements to cooperate and exchange confidential supervisory information with EIOPA and supervisory authorities as defined in Article 13(10);

(f) it has an independent system of supervision;

(g) it has established obligations on professional secrecy for all persons acting on behalf of its supervisory authorities, in particular on the exchange of information with EIOPA and supervisory authorities as defined in Article 13(10).

Any delegated acts on temporary equivalence shall take into account the reports by the Commission in accordance with Article 177(2). Those delegated acts shall be regularly reviewed, on the basis of progress reports by the relevant third country, which are presented to and assessed by the Commission annually. EIOPA shall assist the Commission in the assessment of those progress reports.

EIOPA shall publish and keep up to date on its website a list of all third countries referred to in the first subparagraph.

The Commission may adopt delegated acts in accordance with Article 301a further specifying the conditions laid down in the first subparagraph. Delegated acts may also cover powers for supervisory authorities to impose additional supervisory reporting requirements during the period of temporary equivalence.

6. The limited period referred to in paragraph 5 shall end on 31 December 2020 or on the date on which, in accordance with paragraph 3, the prudential regime of that third country has been deemed to be equivalent to that laid down in this Title, whichever is the earlier.

That period may be extended by a maximum of one more year, where such time is necessary for EIOPA and the Commission to carry out the assessment of equivalence for the purposes of paragraph 3.

7. Where a delegated act determining that the prudential regime of a third country is temporarily equivalent is adopted in accordance with paragraph 5, Member States shall apply Article 261, unless there is an insurance or reinsurance undertaking situated in a Member State which has a balance sheet total that exceeds the balance sheet total of the parent undertaking situated outside the Union. In that case, the task of the group supervisor shall be exercised by the acting group supervisor.';

(76) in Article 262(1), the first subparagraph is replaced by the following:

'1. In the absence of equivalent supervision referred to in Article 260, or where a Member State does not apply Article 261 in the event of temporary equivalence in accordance with Article 260(7), that Member State shall apply either of the following to insurance and reinsurance undertakings:

(a) Articles 218 to 235, and Articles 244 to 258, *mutatis mutandis*;

(b) one of the methods set out in paragraph 2.';

(77) in Article 300, the first paragraph is replaced by the following:

'The amounts expressed in euro in this Directive shall be revised every five years, by increasing the base amount in euro by the percentage change in the Harmonised Indices of Consumer Prices of all Member States as published by the Commission (Eurostat) starting from 31 December 2015 until the date of revision and rounded up to a multiple of EUR 100 000.';

(78) Article 301 is replaced by the following:

'*Article 301*

Committee procedure

1. The Commission shall be assisted by the European Insurance and Occupational Pensions Committee established by Commission Decision 2004/9/EC (*). 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.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.

Article 301a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 17, 31, 35, 37, 50, 56, 75, 86, 92, 97, 99, 109a, 111, 114, 127, 130, 135, 143, 172, 210, 211, 216, 217, 227, 234, 241, 244, 245, 247, 248, 256, 258, 260 and 308b shall be conferred on the Commission for a period of four years from 23 May 2014.

The Commission shall draw up a report in respect of the delegated power by six months before the end of the four-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 17, 31, 35, 37, 50, 56, 75, 86, 92, 97, 99, 109a, 111, 114, 127, 130, 135, 143, 172, 210, 211, 216, 217, 227, 234, 241, 244, 245, 247, 248, 256, 258, 260 and 308b may be revoked at any time by the European Parliament or by the Council.

A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 17, 31, 35, 37, 50, 56, 75, 86, 92, 97, 99, 109a, 111, 114, 127, 130, 135, 143, 172, 210, 211, 216, 217, 227, 234, 241, 244, 245, 247, 248, 256, 258, 260 or 308b shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or the Council.

Article 301b

Sunrise provision for regulatory technical standards

1. Until 24 May 2016, the Commission shall, when adopting for a first time the regulatory technical standards provided for in Articles 50, 58, 75, 86, 92, 97, 111, 135, 143, 244, 245, 248 and 249 follow the procedure laid down in Article 301a. Any amendments to such delegated acts or, after the transitional period has expired, any new regulatory technical standards shall be adopted in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

2. The delegation of power referred to in paragraph 1 may be revoked at any time by the European Parliament or by the Council in accordance with Article 12 of Regulation (EU) No 1094/2010.

3. By 24 May 2016, EIOPA may submit draft regulatory technical standards to the Commission to adjust to technical developments on the financial markets the delegated acts provided for in Articles 17, 31, 35, 37, 50, 56, 75, 86, 92, 97, 99, 109a, 111, 114, 127, 130, 135, 143, 172, 210, 211, 216, 217, 227, 234, 241, 244, 245, 247, 248, 256, 258, 260 and 308b.

Those draft regulatory technical standards shall be limited to the technical aspects of the delegated acts referred to in the first subparagraph, in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

Power is delegated to the Commission to adopt the regulatory technical standards referred to in the first subparagraph in accordance with Articles 10 to 14 of Regulation (EU) No 1094/2010.

(*) Commission Decision 2004/9/EC of 5 November 2003 establishing the European Insurance and Occupational Pensions Committee (OJ L 3, 7.1.2004, p. 34).';

(79) in Article 304, paragraph 2 is replaced by the following:

'2. The Commission shall submit to the European Parliament and to the Council, by 31 December 2020, a report on the application of the approach set out in paragraph 1 and the supervisory authorities' practices adopted pursuant to paragraph 1, accompanied, where appropriate, by adequate proposals. That report shall address, in particular, cross-border effects of the use of that approach with a view to preventing regulatory arbitrage by insurance and reinsurance undertakings.';

(80) the following section is added in Title VI, Chapter I:

'SECTION 3

INSURANCE AND REINSURANCE

Article 308a

Phasing-in

1. From 1 April 2015, Member States shall ensure that the supervisory authorities have the power to decide on the approval of:

(a) ancillary own funds in accordance with Article 90;

(b) the classification of own funds items referred to in the third paragraph of Article 95;

(c) undertaking specific parameters in accordance with Article 104(7);

(d) a full or partial internal model in accordance with Articles 112 and 113;

(e) special purpose vehicles to be established in their territory in accordance with Articles 211;

(f) ancillary own funds of an intermediate insurance holding company in accordance with Article 226(2);

(g) a group internal model in accordance with Article 230, Article 231 and Article 233(5);

(h) the use of the duration based equity risk sub-module in accordance with Article 304;

(i) the use of the matching adjustment to the relevant risk-free interest rate term structure in accordance with Articles 77b and 77c;

(j) where Member States so require, the use of the volatility adjustment to the relevant risk-free interest rate term structure in accordance with Article 77d;

(k) the use of the transitional measure on the risk-free interest rates in accordance with Article 308c;

(l) the use of the transitional measure on technical provisions in accordance with Article 308d.

2. From 1 April 2015, Member States shall ensure that the supervisory authorities have the power to:

(a) determine the level and scope of group supervision in accordance with Title III, Chapter I, Sections 2 and 3;

(b) identify the group supervisor in accordance with Article 247;

(c) establish a college of supervisors in accordance with Article 248.

3. From 1 July 2015, Member States shall ensure that the supervisory authorities have the power to:

(a) decide to deduct any participation in accordance with the second subparagraph of Article 228;

(b) determine the choice of method to calculate group solvency in accordance with Article 220;

(c) make the determination on equivalence, where appropriate, in accordance with Articles 227 and 260;

(d) permit insurance and reinsurance undertakings to be subject to Articles 238 and 239, in accordance with Article 236;

(e) make the determinations referred to in Articles 262 and 263;

(f) determine, where appropriate, the application of transitional measures in accordance with Article 308b.

4. Member States shall oblige the supervisory authorities concerned to consider applications submitted by insurance and reinsurance undertakings for approval or permission in accordance with paragraphs 2 and 3. The decisions taken by the supervisory authorities on applications for approval or permission shall not become applicable before 1 January 2016.

Article 308b

Transitional measures

1. Without prejudice to Article 12, insurance or reinsurance undertakings which, by 1 January 2016, cease to conduct new insurance or reinsurance contracts and exclusively administer their existing portfolio in order to terminate their activity shall not be subject to Titles I, II and III of this Directive until the dates set out in paragraph 2 where either:

(a) the undertaking has satisfied the supervisory authority that it will terminate its activity before 1 January 2019; or

(b) the undertaking is subject to reorganisation measures set out in Title IV, Chapter II and an administrator has been appointed.

2. Insurance or reinsurance undertakings falling under:

(a) paragraph 1(a) shall be subject to Titles I, II and III of this Directive from 1 January 2019 or from an earlier date where the supervisory authority is not satisfied with the progress that has been made towards terminating the undertaking's activity;

(b) paragraph 1(b) shall be subject to Titles I, II and III of this Directive from 1 January 2021 or from an earlier date where the supervisory authority is not satisfied with the progress that has been made towards terminating the undertaking's activity.

3. Insurance and reinsurance undertakings shall be subject to the transitional measures in paragraphs 1 and 2 only if the following conditions are met:

(a) the undertaking is not part of a group, or if it is, all undertakings that are part of the group cease to conduct new insurance or reinsurance contracts;

(b) the undertaking shall provide its supervisory authority with an annual report setting out what progress has been made in terminating its activity;

(c) the undertaking has notified its supervisory authority that it applies the transitional measures.

Paragraphs 1 and 2 shall not prevent any undertaking from operating in accordance with Titles I, II and III of this Directive.

4. Member States shall draw up a list of the insurance and reinsurance undertakings concerned and communicate that list to all the other Member States.

5. Member States shall ensure that, for a period not exceeding four years from 1 January 2016, the deadline for insurance and reinsurance undertakings to submit the information referred to in Article 35(1) to (4) on an annual or less frequent basis shall decrease by two weeks each financial year, starting from no later than 20 weeks after the undertaking's financial year end in relation to its financial year ending on or after 30 June 2016 but before 1 January 2017, to no later than 14 weeks after the undertaking's financial year end in relation to its financial years ending on or after 30 June 2019 but before 1 January 2020.

6. For a period not exceeding four years from 1 January 2016, the deadline for insurance and reinsurance undertakings to disclose the information referred to in Article 51 shall decrease by two weeks each financial year, starting from no later than 20 weeks after the undertaking's financial year end in relation to its financial year ending on or after 30 June 2016 but before 1 January 2017, to no later than 14 weeks after the undertaking's financial year end in relation to its financial years ending on or after 30 June 2019 but before 1 January 2020.

7. For a period not exceeding four years from 1 January 2016, the deadline for insurance and reinsurance undertakings to submit the information referred to in Article 35(1) to (4) on a quarterly basis shall decrease by one week each financial year, starting from no later than eight weeks related to any quarter ending on or after 1 January 2016 but before 1 January 2017, to five weeks related to any quarter ending on or after 1 January 2019 but before 1 January 2020.

8. Member States shall ensure that paragraphs 5, 6 and 7 of this Article shall apply *mutatis mutandis* to participating insurance and reinsurance undertakings, insurance holding companies and mixed financial holding companies at the level of the group pursuant to Articles 254 and 256, whereby the deadlines referred to in paragraphs 5, 6 and 7 shall be extended by six weeks respectively.

9. Notwithstanding Article 94, basic own-fund items shall be included in Tier 1 basic own funds for up to 10 years after 1 January 2016, provided that those items:

(a) were issued before 1 January 2016 or prior to the date of entry into force of the delegated act referred to in Article 97, whichever is the earlier;

(b) on 31 December 2015 could be used to meet the available solvency margin up to 50 % of the solvency margin according to the laws, regulations and administrative provisions which are adopted pursuant to Article 16(3) of Directive 73/239/EEC, Article 1 of Directive 2002/13/EC, Article 27(3) of Directive 2002/83/EC and Article 36(3) of Directive 2005/68/EC;

(c) would not otherwise be classified in Tier 1 or Tier 2 in accordance with Article 94.

10. Notwithstanding Article 94, basic own-fund items shall be included in Tier 2 basic own funds for up to 10 years after 1 January 2016, provided that those items:

(a) were issued before 1 January 2016 or prior to the date of entry into force of the delegated act referred to in Article 97, whichever is the earlier;

(b) on 31 December 2015 could be used to meet the available solvency margin up to 25 % of the solvency margin according to the laws, regulations and administrative provisions which are adopted pursuant to Article 16(3) of Directive 73/239/EEC, Article 1 of Directive 2002/13/EC, Article 27(3) of Directive 2002/83/EC and Article 36(3) of Directive 2005/68/EC.

11. With respect to insurance and reinsurance undertakings investing in tradable securities or other financial instruments based on repackaged loans that were issued before 1 January 2011, the requirements referred to in Article 135(2) shall apply only in circumstances where new underlying exposures were added or substituted after 31 December 2014.

12. Notwithstanding Article 100, Article 101(3) and Article 104, the following shall apply:

(a) until 31 December 2017 the standard parameters to be used when calculating the concentration risk sub-module and the spread risk sub-module in accordance with the standard formula shall be the same in relation to exposures to Member States' central governments or central banks denominated and funded in the domestic currency of any Member State as the ones that would be applied to such exposures denominated and funded in their domestic currency;

(b) in 2018 the standard parameters to be used when calculating the concentration risk sub-module and the spread risk sub-module in accordance with the standard formula shall be reduced by 80 % in relation to exposures to Member States' central governments or central banks denominated and funded in the domestic currency of any other Member State;

(c) in 2019 the standard parameters to be used when calculating the concentration risk sub-module and the spread risk sub-module in accordance with the standard formula shall be reduced by 50 % in relation to exposures to Member States' central governments or central banks denominated and funded in the domestic currency of any other Member State;

(d) from 1 January 2020 the standard parameters to be used when calculating the concentration risk sub-module and the spread risk sub-module in accordance with the standard formula shall not be reduced in relation to exposures to Member States' central governments or central banks denominated and funded in the domestic currency of any other Member State.

13. Notwithstanding Article 100, Article 101(3) and Article 104, the standard parameters to be used for equities that the undertaking purchased on or before 1 January 2016, when calculating the equity risk sub-module in accordance with the standard formula without the option set out in Article 304 shall be calculated as the weighted averages of:

(a) the standard parameter to be used when calculating the equity risk sub-module in accordance with Article 304; and

(b) the standard parameter to be used when calculating the equity risk sub-module in accordance with the standard formula without the option set out in Article 304.

The weight for the parameter expressed in point (b) of the first subparagraph shall increase at least linearly at the end of each year from 0 % during the year starting on 1 January 2016 to 100 % on 1 January 2023.

The Commission shall adopt delegated acts in accordance with Article 301a further specifying the criteria to be met, including the equities that may be subject to the transitional period.

In order to ensure uniform conditions of application of that transitional period, EIOPA shall develop draft implementing technical standards on the procedures for the application of this paragraph.

EIOPA shall submit those draft implementing technical standards to the Commission by 30 June 2015.

Power is conferred on the Commission to adopt the implementing technical standards referred to in the fourth subparagraph in accordance with Article 15 of Regulation (EU) No 1094/2010.

14. Notwithstanding Article 138(3) and without prejudice to paragraph 4 of that Article, where insurance and reinsurance undertakings comply with the Required Solvency Margin referred to in Article 16a of Directive 73/239/EEC, Article 28 of Directive 2002/83/EC or Article 37, 38 or 39 of Directive 2005/68/EC respectively as applicable in the law of the Member State on the day before those Directives are repealed pursuant to Article 310 of this Directive but do not comply with the Solvency Capital Requirement in the first year of application of this Directive, the supervisory authority shall require the insurance or reinsurance undertaking concerned to take the necessary measures to achieve the establishment of the level of eligible own funds covering the Solvency Capital Requirement or the reduction of its risk profile to ensure compliance with the Solvency Capital Requirement by 31 December 2017.

The insurance or reinsurance undertaking concerned shall, every three months, submit a progress report to its supervisory authority setting out the measures taken and the progress made to establish the level of eligible own funds covering the Solvency Capital Requirement or to reduce the risk profile to ensure compliance with the Solvency Capital Requirement.

The extension referred to in the first subparagraph shall be withdrawn where that progress report shows that there was no significant progress in achieving the re-establishment of the level of eligible own funds covering the Solvency Capital Requirement or the reduction of the risk profile to ensure compliance with the Solvency Capital Requirement between the date of the observation of non-compliance of the Solvency Capital Requirement and the date of the submission of the progress report.

15. Where, on 23 May 2014, home Member States applied provisions referred to in Article 4 of Directive 2003/41/EC, that home Member States may continue to apply the laws, regulations and administrative provisions that had been adopted by them with a view to complying with Articles 1 to 19, 27 to 30, 32 to 35 and 37 to 67 of Directive 2002/83/EC as in force on the last date of application of Directive 2002/83/EC until 31 December 2019.

The Commission may adopt delegated acts that amend the transitional period prescribed in this paragraph where amendments to Articles 17 to 17c of Directive 2003/41/EC have been adopted before the date specified in this paragraph.

16. Member States may allow the ultimate parent insurance or reinsurance undertaking, during a period until 31 March 2022, to apply for the approval of an internal group model applicable to a part of a group where both the undertaking and the ultimate parent undertaking are located in the same Member State and if this part forms a distinct part having a significantly different risk profile from the rest of the group.

17. Notwithstanding Articles 218(2) and (3), the transitional provisions as referred to in paragraph 8 to 12 and 15 of this Article and Articles 308c, 308d and 308e shall apply *mutatis mutandis* at the level of the group.

Notwithstanding Article 218(2), (3) and (4), the transitional provisions as referred to in paragraph 14 of this Article shall apply *mutatis mutandis* at the level of the group and where the participating insurance or reinsurance undertakings or the insurance and reinsurance undertakings in a group comply with the Adjusted Solvency referred to in Article 9 of Directive 98/78/EC but do not comply with the group Solvency Capital Requirement.

The Commission shall adopt delegated acts in accordance with Article 301a setting out the changes in the group solvency where the transitional provisions referred to in paragraph 13 of this Article are applicable and which relate to:

(a) the elimination of double use of eligible own funds and of the intra-group creation of capital set out in Articles 222 and 223;

(b) the valuation of assets and liabilities set out in Article 224;

(c) the application of the calculation methods to related insurance and reinsurance undertakings set out in Article 225;

(d) the application of the calculation methods to intermediate insurance holding companies set out in Article 226;

(e) the methods for calculating group solvency set out in Articles 230 and 233;

(f) the calculation of the group Solvency Capital Requirement set out in Articles 231;

(g) the setting of a capital add-on set out in Article 232;

(h) the principles in calculating group solvency of an insurance holding company set out in Article 235.

Article 308c

Transitional measure on the risk-free interest rates

1. Insurance and reinsurance undertakings may, subject to prior approval by their supervisory authority, apply a transitional adjustment to the relevant risk-free interest rate term structure with respect to admissible insurance and reinsurance obligations.

2. For each currency the adjustment shall be calculated as a portion of the difference between:

(a) the interest rate as determined by the insurance or reinsurance undertaking in accordance with the laws, regulations and administrative provisions which are adopted pursuant to Article 20 of Directive 2002/83/EC at the last date of the application of that Directive;

(b) the annual effective rate, calculated as the single discount rate that, where applied to the cash flows of the portfolio of admissible insurance and reinsurance obligations, results in a value that is equal to the value of the best estimate of the portfolio of admissible insurance and reinsurance obligations where the time value of money is taken into account using the relevant risk-free interest rate term structure referred to in Article 77(2).

Where Member States have adopted laws, regulations and administrative provisions pursuant to Article 20(1)B(a)(ii) of Directive 2002/83/EC, the interest rate referred to in point (a) of the first subparagraph of this paragraph shall be determined using the methods used by the insurance or reinsurance undertaking at the last date of the application of Directive 2002/83/EC.

The portion referred to in the first subparagraph shall decrease linearly at the end of each year from 100 % during the year starting from 1 January 2016 to 0 % on 1 January 2032.

Where insurance and reinsurance undertakings apply the volatility adjustment referred to in Article 77d, the relevant risk-free interest rate term structure referred to in point (b) shall be the adjusted relevant risk-free interest rate term structure set out in Article 77d.

3. The admissible insurance and reinsurance obligations shall comprise only insurance or reinsurance obligations that meet the following requirements:

(a) the contracts that give rise to the insurance and reinsurance obligations were concluded before the first date of the application of this Directive, excluding contract renewals on or after that date;

(b) until the last date of the application of Directive 2002/83/EC, technical provisions for the insurance and reinsurance obligations were determined in accordance with the laws, regulations and administrative provisions which are adopted pursuant to Article 20 of that Directive at the last date of the application thereof;

(c) Article 77b is not applied to the insurance and reinsurance obligations.

4. Insurance and reinsurance undertakings applying paragraph 1 shall:

(a) not include the admissible insurance and reinsurance obligations in the calculation of the volatility adjustment set out in Article 77d;

(b) not apply Article 308d;

(c) as part of their report on their solvency and financial condition referred to in Article 51, publicly disclose that they apply the transitional risk-free interest rate term structure, and the quantification of the impact of not applying this transitional measure on their financial position.

Article 308d

Transitional measure on technical provisions

1. Insurance and reinsurance undertakings may, subject to prior approval by their supervisory authority, apply a transitional deduction to technical provisions. That deduction may be applied at the level of homogeneous risk groups referred to in Article 80.

2. The transitional deduction shall correspond to a portion of the difference between the following two amounts:

(a) the technical provisions after deduction of the amounts recoverable from reinsurance contracts and special purpose vehicles, calculated in accordance with Article 76 at the first date of the application of this Directive;

(b) the technical provisions after deduction of the amounts recoverable from reinsurance contracts calculated in accordance with the laws, regulations and administrative provisions which are adopted pursuant to Article 15 of Directive 73/239/EEC, Article 20 of Directive 2002/83/EC and Article 32 of Directive 2005/68/EC on the day before those Directives are repealed pursuant to Article 310 of this Directive.

The maximum portion deductible shall decrease linearly at the end of each year from 100 % during the year starting from 1 January 2016 to 0 % on 1 January 2032.

Where insurance and reinsurance undertakings apply at the first date of the application of this Directive the volatility adjustment referred to in the Article 77d, the amount referred to in point (a) shall be calculated with the volatility adjustment at that date.

3. Subject to prior approval by or on the initiative of the supervisory authority, the amounts of technical provisions, including where applicable the amount of the volatility adjustment, used to calculate the transitional deduction referred to in paragraph 2(a) and (b) may be recalculated every 24 months, or more frequently where the risk profile of the undertaking has materially changed.

4. The deduction referred to in paragraph 2 may be limited by the supervisory authority if its application could result in a reduction of the financial resources requirements that apply to the undertaking when compared with those calculated in accordance with the laws, regulations and administrative provisions which are adopted pursuant to Directive 73/239/EEC, Directive 2002/83/EC and Directive 2005/68/EC on the day before those Directives are repealed pursuant to Article 310 of this Directive.

5. Insurance and reinsurance undertakings applying paragraph 1 shall:

(a) not apply Article 308c;

(b) when they would not comply with the Solvency Capital Requirement without application of the transitional deduction, submit annually a report to their supervisory authority setting out measures taken and the progress made to re-establish at the end of the transitional period set out in paragraph 2 a level of eligible own funds covering the Solvency Capital Requirement or to reduce their risk profile to restore compliance with the Solvency Capital Requirement;

(c) as part of their report on their solvency and financial condition referred to in Article 51, publicly disclose that they apply the transitional deduction to the technical provisions, and the quantification of the impact of not applying that transitional deduction on their financial position.

Article 308e

Phasing-in plan on the transitional measures on risk-free interest rates and on technical provisions

Insurance and reinsurance undertakings that apply the transitional measures set out in Articles 308c or 308d shall inform the supervisory authority as soon as they observe that they would not comply with the Solvency Capital Requirement without application of these transitional measures. The supervisory authority shall require the insurance or reinsurance undertaking concerned to take the necessary measures to ensure compliance with the Solvency Capital Requirement at the end of the transitional period.

Within two months from observation of non-compliance with the Solvency Capital Requirement without application of these transitional measures, the insurance or reinsurance undertaking concerned shall submit to the supervisory authority a phasing-in plan setting out the planned measures to establish the level of eligible own funds covering the Solvency Capital Requirement or to reduce its risk profile to ensure compliance with the Solvency Capital Requirement at the end of the transitional period. The insurance or reinsurance undertaking concerned may update the phasing-in plan during the transitional period.

The insurance and reinsurance undertakings concerned shall submit annually a report to their supervisory authority setting out the measures taken and the progress made to ensure compliance with the Solvency Capital Requirement at the end of the transitional period. Supervisory authorities shall revoke the approval for the application of the transitional measure where that progress report shows that compliance with the Solvency Capital Requirement at the end of the transitional period is unrealistic.';

(81) Article 309(1) is amended as follows:

(a) the first subparagraph is replaced by the following:

'1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 4, 10, 13, 14, 18, 23, 26 to 32, 34 to 49, 51 to 55, 67, 68, 71, 72, 74 to 85, 87 to 91, 93 to 96, 98, 100 to 110, 112, 113, 115 to 126, 128, 129, 131 to 134, 136 to 142, 144, 146, 148, 162 to 167, 172, 173, 178, 185, 190, 192, 210 to 233, 235 to 240, 243 to 258, 260 to 263, 265, 266, 303 and 304, and Annexes III and IV by 31 March 2015. They shall forthwith communicate to the Commission the text of those measures.';

(b) the following subparagraph is added:

'Notwithstanding the second subparagraph, Member States shall apply the laws, regulations and administrative provisions necessary to comply with Article 308a from 1 April 2015.';

(82) the following article is inserted:

'Article 310a

Staff and resources of EIOPA

EIOPA shall asses the staffing and resources needs arising from the assumption of its powers and duties in accordance with this Directive and shall submit a report to the European Parliament, the Council and the Commission in relation thereto.';

(83) Article 311 is replaced by the following:

'Article 311

Entry into force

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

Article 308a shall apply from 1 April 2015.

Articles 1, 2, 3, 5 to 9, 11, 12, 15, 16, 17, 19 to 22, 24, 25, 33, 57 to 66, 69, 70, 73, 145, 147, 149 to 161, 168 to 171, 174 to 177, 179 to 184, 186 to 189, 191, 193 to 209, 267 to 300, 302, 305 to 308, 308b and Annexes I and II, V, VI and VII shall apply from 1 January 2016.

The Commission may adopt delegated acts and regulatory and implementing technical standards prior to the date referred to in the third paragraph.';

(84) in Annex III, part A, point 28 is replaced by the following:

'(28) in any event and as an alternative to the forms of non-life insurance undertaking listed in points (1) to (27) and (29), the form of a European Company (SE) as defined in Council Regulation (EC) No 2157/2001(1);

(29) to the extent that the Member State concerned allows for the legal form of a cooperative society to take up the business of non-life insurance and as an alternative to the forms of non-life insurance undertaking listed in points (1) to (28), the form of a European Cooperative Society in accordance with Council Regulation (EC) No 1435/2003 (*)

(*) Council Regulation (EC) No 1435/2003 of 22 July 2003 on the Statute for a European Cooperative Society (SCE) (OJ L 207, 18.8.2003, p. 1).';.

(85) in Annex III, part B, point 28 is replaced by the following:

'(28) in any event and as an alternative to the forms of life insurance undertaking listed in points (1) to (27) and (29), the form of a European Company (SE) as defined in Regulation (EC) No 2157/2001;

(29) to the extent that the Member State concerned allows for the legal form of a cooperative society to take up the business of life insurance and as an alternative to the forms of life insurance undertaking listed in points (1) to (28), the form of a European Cooperative Society in accordance with Regulation (EC) No 1435/2003.';

(86) in Annex III, part C, point 28 is replaced by the following:

'(28) in any event and as an alternative to the forms of reinsurance undertaking listed in points (1) to (27) and (29), the form of a European Company (SE) as defined in Regulation (EC) No 2157/2001;

(29) to the extent that the Member State concerned allows for the legal form of a cooperative society to take up the business of reinsurance and as an alternative to the forms of reinsurance undertaking listed in points (1) to (28), the form of a European Cooperative Society in accordance with Regulation (EC) No 1435/2003.';

(87) in the correlation table in Annex VII, under the column 'This Directive', Article 13(27) is inserted as corresponding to Article 5(d) of Directive 73/239/EEC.

Article 3

Amendments to Regulation (EC) No 1060/2009

In Regulation (EC) No 1060/2009, Article 2(3) is deleted.

Article 4

Amendments to Regulation (EU) No 1094/2010

Regulation (EU) No 1094/2010 is amended as follows:

(1) in Article 13, paragraph 1 is replaced by the following:

'1. The European Parliament or the Council may object to a regulatory technical standard within a period of three months from the date of notification of the regulatory technical standard adopted by the Commission. At the initiative of the European Parliament or of the Council that period shall be extended by three months.

Where the Commission adopts a regulatory technical standard which is the same as the draft regulatory technical standard submitted by the Authority, the period during which the European Parliament and the Council may object shall be one month from the date of notification. At the initiative of the European Parliament or the Council that period shall be extended by one month. That extended period may be further extended by one month at initiative of the European Parliament or the Council.';

(2) in Article 17(2), the second subparagraph is replaced by the following:

'Without prejudice to the powers laid down in Article 35, the competent authority shall, without delay, provide the Authority with all information which the Authority considers necessary for its investigation, including with regard to how the acts referred to in Article 1(2) are applied in accordance with Union law.'.

Article 5

Amendments to Regulation (EU) No 1095/2010

Regulation (EU) No 1095/2010 is amended as follows:

(1) in Article 13, paragraph 1 is replaced by the following:

'1. The European Parliament or the Council may object to a regulatory technical standard within a period of three months from the date of notification of the regulatory technical standard adopted by the Commission. At the initiative of the European Parliament or the Council that period shall be extended by three months.

Where the Commission adopts a regulatory technical standard which is the same as the draft regulatory technical standard submitted by the Authority, the period during which the European Parliament and the Council may object shall be one month from the date of notification. At the initiative of the European Parliament or the Council that period shall be extended by one month. That extended period may be further extended by one month at initiative of the European Parliament or the Council.';

(2) in Article 17(2), the second subparagraph is replaced by the following:

'Without prejudice to the powers laid down in Article 35, the competent authority shall, without delay, provide the Authority with all information which the Authority considers necessary for its investigation, including with regard to how the acts referred to in Article 1(2) are applied in accordance with Union law.'.

Article 6

Revision

The Commission shall, by 1 January 2017 and annually thereafter, submit to the European Parliament and to the Council a report specifying whether the ESAs have submitted the draft regulatory technical standards and implementing technical standards provided for in Directives 2003/71/EC and 2009/138/EC, whether the submission of such draft regulatory technical standards or implementing technical standards is mandatory or optional, together with proposals, where appropriate.

Article 7

Transposition

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with Article 1(1) and Article 2(1), (3), (6) to (11), (13), (14), (17) to (23), (32), (34), (36), (38) to (44), (46) to (54), (56) to (59), (65) to (70), (72), (75), (76), (80), (81), (84), (85) and (86) by 31 March 2015. They shall forthwith communicate to the Commission the text of those measures.

2. They shall apply the measures referred to in paragraph 1 from 1 January 2016.

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

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

Article 8

Entry into force

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

Article 2(25), (43) and (82) shall apply from 31 March 2015.

Article 9

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 16 April 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

(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 Economic and Social Committee ([1]),

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Directive 1999/5/EC of the European Parliament and of the Council ([3]) has been substantially amended several times. Since further amendments are to be made, it should be replaced in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council ([4]) lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council ([5]) lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 1999/5/EC should therefore be adapted to that Decision.

(4) The essential requirements laid down in Directive 1999/5/EC which are relevant to fixed-line terminal equipment, i.e. to ensure the protection of health and safety of persons and of domestic animals and the protection of property and an adequate level of electromagnetic compatibility, are appropriately covered by Directive 2014/35/EU of the European Parliament and of the Council ([6]) and Directive 2014/30/EU of the European Parliament and of the Council ([7]). This Directive should therefore not apply to fixed-line terminal equipment.

([1]) OJ C 133, 9.5.2013, p. 58.

([2]) Position of the European Parliament of 13 March 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

([3]) Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ L 91, 7.4.1999, p. 10).

([4]) 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).

([5]) 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).

([6]) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).

([7]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).

(5) Competition issues in the market for terminal equipment are appropriately covered by Commission Directive 2008/63/EC ([1]), in particular through the obligation for national regulatory authorities to ensure the publication of details of technical interface specifications for network access. It is therefore not necessary to include in this Directive requirements facilitating competition in the market for terminal equipment covered by Directive 2008/63/EC.

(6) Equipment which intentionally emits or receives radio waves for the purpose of radio communication or radiodetermination makes systematic use of radio spectrum. In order to ensure an efficient use of radio spectrum so as to avoid harmful interference, all such equipment should fall within the scope of this Directive.

(7) The objectives with respect to safety requirements laid down in Directive 2014/35/EU are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions other than those concerning such requirements, Directive 2014/35/EU should not apply to radio equipment.

(8) The essential requirements in the area of electromagnetic compatibility laid down by Directive 2014/30/EU are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions other than those concerning essential requirements, Directive 2014/30/EU should not apply to radio equipment.

(9) This Directive should apply to all forms of supply, including distance selling.

(10) In order to ensure that radio equipment uses the radio spectrum effectively and supports the efficient use of radio spectrum, radio equipment should be constructed so that: in the case of a transmitter, when the transmitter is properly installed, maintained and used for its intended purpose it generates radio waves emissions that do not create harmful interference, while unwanted radio waves emissions generated by the transmitter (e.g. in adjacent channels) with a potential negative impact on the goals of radio spectrum policy should be limited to such a level that, according to the state of the art, harmful interference is avoided; and, in the case of a receiver, it has a level of performance that allows it to operate as intended and protects it against the risk of harmful interference, in particular from shared or adjacent channels, and, in so doing, supports improvements in the efficient use of shared or adjacent channels.

(11) Although receivers do not themselves cause harmful interference, reception capabilities are an increasingly important factor in ensuring the efficient use of radio spectrum by way of an increased resilience of receivers against harmful interference and unwanted signals on the basis of the relevant essential requirements of Union harmonisation legislation.

(12) Interworking via networks with other radio equipment and connection with interfaces of the appropriate type throughout the Union is necessary in some cases. Interoperability between radio equipment and accessories such as chargers simplifies the use of radio equipment and reduces unnecessary waste and costs. A renewed effort to develop a common charger for particular categories or classes of radio equipment is necessary, in particular for the benefit of consumers and other end-users; this Directive should therefore include specific requirements in that area. In particular, mobile phones that are made available on the market should be compatible with a common charger.

(13) The protection of personal data and privacy of users and of subscribers of radio equipment and the protection from fraud may be enhanced by particular features of radio equipment. Radio equipment should therefore in appropriate cases be designed in such a way that it supports those features.

([1]) Commission Directive 2008/63/EC of 20 June 2008 on competition in the markets in telecommunications terminal equipment (OJ L 162, 21.6.2008, p. 20).

(14) Radio equipment can be instrumental in providing access to emergency services. Radio equipment should therefore in appropriate cases be designed in such a way that it supports the features required for access to those services.

(15) Radio equipment is important to the well-being and employment of people with disabilities, who represent a substantial and growing proportion of the population of Member States. Radio equipment should therefore in appropriate cases be designed in such a way that people with disabilities may use it without or with only minimal adaptation.

(16) The compliance of some categories of radio equipment with the essential requirements set out in this Directive may be affected by the inclusion of software or modification of its existing software. The user, the radio equipment or a third party should only be able to load software into the radio equipment where this does not compromise the subsequent compliance of that radio equipment with the applicable essential requirements.

(17) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(18) In order to effectively address the needs related to interoperability, protection of personal data and privacy of the user and of the subscriber, protection from fraud, access to emergency services, use by users with a disability or the prevention of non-compliant combinations of radio equipment and software, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the specification of categories or classes of radio equipment that have to comply with one or more of the additional essential requirements set out in this Directive which address those needs.

(19) Verification by radio equipment of the compliance of its combination with software should not be abused in order to prevent its use with software provided by independent parties. The availability to public authorities, manufacturers and users of information on the compliance of intended combinations of radio equipment and software should contribute to facilitate competition. In order to achieve those objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the specification of categories or classes of radio equipment for which manufacturers have to provide information on the compliance of intended combinations of radio equipment and software with the essential requirements set out in this Directive.

(20) A requirement to register in a central system radio equipment to be placed on the market may enhance the efficiency and effectiveness of market surveillance and thereby contribute to ensuring a high level of compliance with this Directive. Such a requirement entails additional burden to economic operators and should therefore be introduced only for those categories of radio equipment where a high level of compliance has not been attained. In order to ensure the application of such a requirement, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the specification of the categories of radio equipment which manufacturers have to register within a central system and the elements of the technical documentation to be provided on the basis of the information on the compliance of radio equipment to be provided by Member States and following an evaluation of the risk of non-implementation of the essential requirements.

(21) Radio equipment which complies with the relevant essential requirements should be allowed to circulate freely. Such equipment should be allowed to be put into service and used for its intended purpose, where applicable in accordance with rules on authorisations for the use of radio spectrum and the provision of the service concerned.

(22) In order to avoid unnecessary barriers to trade in radio equipment within the internal market, Member States should notify, under Directive 98/34/EC of the European Parliament and of the Council ([1]), other Member States and the Commission of their projects in the area of technical regulations, such as radio interfaces, unless those technical regulations allow Member States to comply with binding Union acts such as Commission decisions on the harmonised use of radio spectrum adopted under Decision No 676/2002/EC of the European Parliament and of the Council ([2]), or where they correspond to radio equipment which can be put into service and used without restrictions within the Union.

(23) The provision of information on the equivalence of regulated radio interfaces and their conditions of use reduces barriers for the access of radio equipment to the internal market. The Commission should therefore assess and establish the equivalence of regulated radio interfaces and make such information available in the form of radio equipment classes.

(24) In accordance with Commission Decision 2007/344/EC ([3]), Member States are to use the Frequency Information System (EFIS) of the European Communications Office (ECO) in order to make comparable information regarding the use of radio spectrum in each Member State available to the public via the internet. Manufacturers can search in EFIS frequency information for all Member States prior to the placing on the market of radio equipment and thereby evaluate whether and under which conditions such radio equipment may be used within each Member State. There is therefore no need to include in this Directive additional provisions, such as prior notification, allowing manufacturers to be informed of the conditions of use of radio equipment using non-harmonised frequency bands.

(25) For the purpose of promotion of research and demonstration activities it should be possible, in the context of trade fairs, exhibitions and similar events, to display radio equipment which does not comply with this Directive and cannot be placed on the market, on the condition that exhibitors ensure that sufficient information is provided to the visiting public.

(26) Economic operators should be responsible for the compliance of radio equipment with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of health and safety of persons and of domestic animals, and the protection of property, an adequate level of electromagnetic compatibility, an effective and efficient use of radio spectrum and, where necessary, a high level of protection of other public interests, and to guarantee fair competition on the Union market.

(27) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market radio equipment which is in conformity with this Directive. 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.

(28) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.

(29) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

([1]) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

([2]) Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision) (OJ L 108, 24.4.2002, p. 1).

([3]) Commission Decision 2007/344/EC of 16 May 2007 on harmonised availability of information regarding spectrum use within the Community (OJ L 129, 17.5.2007, p. 67).

(30) The manufacturer should provide sufficient information on the intended use of the radio equipment so as to allow its use in compliance with the essential requirements. Such information may need to include a description of accessories such as antennas and of components such as software, and specifications of the installation process of the radio equipment.

(31) The requirement laid down in Directive 1999/5/EC to include an EU declaration of conformity with equipment has been found to simplify and to enhance the information and the efficiency of market surveillance. The possibility to provide a simplified EU declaration of conformity has allowed the burden associated with this requirement to be reduced without reduction of its effectiveness, and should therefore be provided for within this Directive. Furthermore, in order to ensure easy and efficient access to an EU declaration of conformity, including a simplified EU declaration of conformity, it should be possible to affix it to the packaging of the radio equipment concerned.

(32) It is necessary to ensure that radio equipment from third countries entering the Union market complies with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that radio equipment. Provision should therefore be made for importers to make sure that the radio equipment they place on the market complies with the requirements of this Directive and that they do not place on the market radio equipment which does not comply with such requirements or presents a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of radio equipment and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

(33) When placing radio equipment on the market, every importer should indicate on the radio equipment 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 radio equipment does not allow it. This includes cases where the importer would have to open the packaging in order to put his name and address on the radio equipment.

(34) The distributor makes radio equipment 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 radio equipment does not adversely affect the compliance of the radio equipment.

(35) Any economic operator that either places radio equipment on the market under his own name or trade mark or modifies radio equipment in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(36) 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 radio equipment concerned.

(37) Ensuring traceability of radio equipment 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 radio equipment available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with radio equipment or to whom they have supplied radio equipment.

(38) This Directive should be limited to the expression of essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for radio equipment which is in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council [1] for the purpose of expressing detailed technical specifications of those requirements.

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[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, 14.11.2012, p. 12).

(39) 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 Directive.

(40) In order to enable economic operators to demonstrate and the competent authorities to ensure that radio equipment made available on the market conforms 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.

(41) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of radio equipment with the requirements of this Directive and of the other relevant Union harmonisation legislation.

(42) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

(43) The CE marking, indicating the conformity of radio equipment, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.

(44) The requirement to affix the CE marking on products is important for the information of consumers and public authorities. The possibility laid down in Directive 1999/5/EC to affix a reduced CE mark on small-sized equipment, provided that it remains visible and legible, has allowed the application of that requirement to be simplified without reducing its effectiveness, and should therefore be included in this Directive.

(45) The requirement laid down in Directive 1999/5/EC to affix the CE marking on the packaging of equipment has been found to simplify the task of market surveillance, and should therefore be included in this Directive.

(46) Member States should take appropriate measures to ensure that radio equipment may be made available on the market only if, when properly installed and maintained and used for its intended purpose, it complies with the essential requirements set out in this Directive, and, in the case of the essential requirement to ensure the protection of the health and safety of persons and of domestic animals and the protection of property, also under conditions of use which can be reasonably foreseen. Radio equipment should be considered as non-compliant with that essential requirement only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

(47) In view of the rapid pace of technological change towards a paperless environment, where radio equipment is fitted with an integral screen, the Commission should examine, as part of a review of the operation of this Directive, the feasibility of replacing the requirements for affixing: the manufacturer's name, registered trade name or registered trade mark and a single point or postal address at which they can be contacted, CE marking and EU declaration of conformity with either a function whereby such information is automatically displayed upon starting up the radio equipment, or a function allowing the end-user to select the display of the relevant information. Furthermore, as part of that examination of feasibility, where radio equipment fitted with an integral screen operates from an integral battery which does not hold an initial charge, the Commission should also consider the use of removable transparent integral screen covering labels which would display the same information.

(48) Certain conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

(49) Experience has shown that the criteria set out in Directive 1999/5/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified 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.

(50) 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 Directive.

(51) 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.

(52) The system set out in this Directive 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.

(53) 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.

(54) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for radio equipment 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.

(55) 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.

(56) Since notified 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.

(57) In the interests of competitiveness, it is crucial that notified bodies 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 notified bodies.

(58) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to radio equipment covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(59) Directive 1999/5/EC already provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(60) The decisions of the Commission adopted under Decision No 676/2002/EC may include conditions for the availability and efficient use of radio spectrum which may have as a consequence the limitation of the total number of items of radio equipment put into service, such as a 'sunset' date, a maximum penetration rate or a maximum number of items of radio equipment in each Member State or throughout the Union. Those conditions enable the market to be opened up to new radio equipment while limiting the risk of harmful interference by accumulation of an excessive number of items of radio equipment put into service, even though that equipment individually complies with the essential requirements set out in this Directive. Infringing such conditions may create a risk to the essential requirements, particularly a risk of harmful interference.

(61) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to radio equipment presenting a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such equipment.

(62) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(63) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council [1].

(64) The advisory procedure should be used for the adoption of implementing acts specifying how to present information in cases of restrictions on putting into service or of existing requirements for authorisation of use; and requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet or no longer meets the requirements for its notification.

(65) The examination procedure should be used for the adoption of implementing acts: determining whether certain categories of electrical or electronic products meet the definition of 'radio equipment'; laying down the operational rules for making the information on compliance available; laying down the operational rules for registration and the operational rules for affixing the registration number on radio equipment; and establishing the equivalence between notified radio interfaces and assigning a radio equipment class. It should also be used with respect to compliant radio equipment which presents a risk to the health or safety of persons or to other aspects of public interest protection.

(66) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant radio equipment which presents a risk to the health or safety of persons, imperative grounds of urgency so require.

(67) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

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[1] 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 Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(68) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

(69) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant radio equipment are justified or not.

(70) The Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

(71) It is necessary to provide for transitional arrangements that allow the making available on the market and putting into service of radio equipment that has already been placed on the market in accordance with Directive 1999/5/EC.

(72) The European Data Protection Supervisor has been consulted.

(73) Since the objective of this Directive, namely to ensure that radio equipment made available on the market fulfils requirements providing a high level of protection of health and safety, adequate level of electromagnetic compatibility and an effective and efficient use of radio spectrum so as to avoid harmful interference while guaranteeing the proper functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather, 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 Directive does not go beyond what is necessary in order to achieve that objective.

(74) Directive 1999/5/EC should be repealed.

(75) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents [1], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Directive establishes a regulatory framework for the making available on the market and putting into service in the Union of radio equipment.

2. This Directive shall not apply to equipment listed in Annex I.

[1] OJ C 369, 17.12.2011, p. 14.

3. This Directive shall not apply to radio equipment exclusively used for activities concerning public security, defence, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law.

4. Radio equipment falling within the scope of this Directive shall not be subject to Directive 2014/35/EU, except as set out in point (a) of Article 3(1) of this Directive.

Article 2

Definitions

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

(1) 'radio equipment' means an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination;

(2) 'radio communication' means communication by means of radio waves;

(3) 'radiodetermination' means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves;

(4) 'radio waves' means electromagnetic waves of frequencies lower than 3 000 GHz, propagated in space without artificial guide;

(5) 'radio interface' means the specification of the regulated use of radio spectrum;

(6) 'radio equipment class' means a class identifying particular categories of radio equipment which, under this Directive, are considered similar and those radio interfaces for which the radio equipment is designed;

(7) 'harmful interference' means harmful interference as defined in point (r) of Article 2 of Directive 2002/21/EC of the European Parliament and of the Council [1];

(8) 'electromagnetic disturbance' means electromagnetic disturbance as defined in point 5 of Article 3(1) of Directive 2014/30/EU;

(9) 'making available on the market' means any supply of radio equipment for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(10) 'placing on the market' means the first making available of radio equipment on the Union market;

(11) 'putting into service' means the first use of radio equipment in the Union by its end-user;

(12) 'manufacturer' means any natural or legal person who manufactures radio equipment or has radio equipment designed or manufactured, and markets that equipment under his name or trade mark;

(13) '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;

(14) 'importer' means any natural or legal person established within the Union who places radio equipment from a third country on the Union market;

[1] Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive) (OJ L 108, 24.4.2002, p. 33).

(15) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market;

(16) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(17) 'technical specification' means a document that prescribes technical requirements to be fulfilled by radio equipment;

(18) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

(19) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(20) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

(21) 'conformity assessment' means the process demonstrating whether the essential requirements of this Directive relating to radio equipment have been fulfilled;

(22) 'conformity assessment body' means a body that performs conformity assessment activities;

(23) 'recall' means any measure aimed at achieving the return of radio equipment that has already been made available to the end-user;

(24) 'withdrawal' means any measure aimed at preventing radio equipment in the supply chain from being made available on the market;

(25) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(26) 'CE marking' means a marking by which the manufacturer indicates that the radio equipment is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

2. The Commission may adopt implementing acts to determine whether certain categories of electrical or electronic products meet the definition set out in point 1 of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

Article 3

Essential requirements

1. Radio equipment shall be constructed so as to ensure:

(a) the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying;

(b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

2. Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

3. Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:

(a) radio equipment interworks with accessories, in particular with common chargers;

(b) radio equipment interworks via networks with other radio equipment;

(c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;

(d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;

(e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;

(f) radio equipment supports certain features ensuring protection from fraud;

(g) radio equipment supports certain features ensuring access to emergency services;

(h) radio equipment supports certain features in order to facilitate its use by users with a disability;

(i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated.

The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories or classes of radio equipment are concerned by each of the requirements set out in points (a) to (i) of the first subparagraph of this paragraph.

Article 4

Provision of information on the compliance of combinations of radio equipment and software

1. Manufacturers of radio equipment and of software allowing radio equipment to be used as intended shall provide the Member States and the Commission with information on the compliance of intended combinations of radio equipment and software with the essential requirements set out in Article 3. Such information shall result from a conformity assessment carried out in accordance with Article 17, and shall be given in the form of a statement of compliance which includes the elements set out in Annex VI. Depending on the specific combinations of radio equipment and software, the information shall precisely identify the radio equipment and the software which have been assessed, and it shall be continuously updated.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories or classes of radio equipment are concerned by the requirement set out in paragraph 1 of this Article.

3. The Commission shall adopt implementing acts laying down the operational rules for making the information on compliance available for the categories and classes specified by the delegated acts adopted pursuant to paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

Article 5

Registration of radio equipment types within some categories

1. As from 12 June 2018, manufacturers shall register radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements set out in Article 3 within a central system referred to in paragraph 4 of this Article prior to radio equipment within those categories being placed on the market. When registering such radio equipment types, manufacturers shall provide some, or where justified all, elements of the technical documentation listed in points (a), (d), (e), (f), (g), (h) and (i) of Annex V. The Commission shall allocate to each registered radio equipment type a registration number, which manufacturers shall affix on radio equipment placed on the market.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 44 specifying which categories of radio equipment are concerned by the requirement set out in paragraph 1 of this Article, and the elements of the technical documentation to be provided, taking into account the information on the compliance of radio equipment provided by Member States in accordance with Article 47(1) and following an evaluation of the risk of non-implementation of the essential requirements.

3. The Commission shall adopt implementing acts laying down the operational rules for registration and the operational rules for affixing the registration number on radio equipment for the categories specified by the delegated acts adopted pursuant to paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

4. The Commission shall make available a central system allowing manufacturers to register the required information. That system shall ensure appropriate control of access to information of confidential nature.

5. Following the date of application of a delegated act adopted pursuant to paragraph 2 of this Article, the reports prepared in accordance with Article 47(1) and (2) shall evaluate its impacts.

Article 6

Making available on the market

Member States shall take appropriate measures to ensure that radio equipment is made available on the market only if it complies with this Directive.

Article 7

Putting into service and use

Member States shall allow the putting into service and use of radio equipment if it complies with this Directive when it is properly installed, maintained and used for its intended purpose. Without prejudice to their obligations under Decision No 676/2002/EC and to the conditions attached to authorisations for the use of frequencies in conformity with Union law, in particular under Article 9(3) and (4) of Directive 2002/21/EC, Member States may only introduce additional requirements for the putting into service and/or use of radio equipment for reasons related to the effective and efficient use of the radio spectrum, to the avoidance of harmful interference, to the avoidance of electromagnetic disturbances or to public health.

Article 8

Notification of radio interface specifications and assignment of radio equipment classes

1. Member States shall notify, in accordance with the procedure set out in Directive 98/34/EC, the radio interfaces which they intend to regulate except:

(a) the radio interfaces which fully and without any deviation comply with the Commission decisions on the harmonised use of radio spectrum adopted pursuant to Decision No 676/2002/EC; and

(b) the radio interfaces which, in accordance with implementing acts adopted pursuant to paragraph 2 of this Article, correspond to radio equipment which can be put into service and used without restrictions within the Union.

2. The Commission shall adopt implementing acts establishing the equivalence between notified radio interfaces and assigning a radio equipment class, details of which shall be published in the *Official Journal of the European Union*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

Article 9

Free movement of radio equipment

1. Member States shall not impede, for reasons relating to aspects covered by this Directive, the making available on the market in their territory of radio equipment which complies with this Directive.

2. At trade fairs, exhibitions and similar events, Member States shall not create any obstacles to the display of radio equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such radio equipment may not be made available on the market or put into service until it has been brought into conformity with this Directive. Demonstration of radio equipment may only take place provided that adequate measures, as prescribed by Member States, have been taken to avoid harmful interference, electromagnetic disturbances and risk to the health or safety of persons or of domestic animals or to property.

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 10

Obligations of manufacturers

1. When placing their radio equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the essential requirements set out in Article 3.

2. Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.

3. Manufacturers shall draw up the technical documentation referred to in Article 21 and carry out the relevant conformity assessment procedure referred to in Article 17 or have it carried out.

Where compliance of radio equipment with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

4. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the radio equipment has been placed on the market.

5. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in radio equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of radio equipment is declared shall be adequately taken into account.

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

6. Manufacturers shall ensure that radio equipment which they have placed on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the radio equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying the radio equipment.

7. Manufacturers shall indicate on the radio equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying the radio equipment. 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 end-users and market surveillance authorities.

8. Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The following information shall also be included in the case of radio equipment intentionally emitting radio waves:

(a) frequency band(s) in which the radio equipment operates;

(b) maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

9. Manufacturers shall ensure that each item of radio equipment is accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. Where a simplified EU declaration of conformity is provided, it shall contain the exact internet address where the full text of the EU declaration of conformity can be obtained.

10. In cases of restrictions on putting into service or of requirements for authorisation of use, information available on the packaging shall allow the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorisation of use exist. Such information shall be completed in the instructions accompanying the radio equipment. The Commission may adopt implementing acts specifying how to present that information. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 45(2).

11. Manufacturers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the radio equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market to that effect, giving details, in particular, of the non-compliance, of any corrective measures taken and of the results thereof.

12. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the radio equipment with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market.

Article 11

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 10(1) and the obligation to draw up technical documentation laid down in Article 10(3) 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 market surveillance authorities for 10 years after the radio equipment 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 radio equipment;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by radio equipment covered by the authorised representative's mandate.

Article 12

Obligations of importers

1. Importers shall place only compliant radio equipment on the market.

2. Before placing radio equipment on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 17 has been carried out by the manufacturer and that the radio equipment is so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum. They shall ensure that the manufacturer has drawn up the technical documentation, that the radio equipment bears the CE marking and is accompanied by the information and documents referred to in Article 10(8), (9) and (10), and that the manufacturer has complied with the requirements set out in Article 10(6) and (7).

Where an importer considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in Article 3, he shall not place the radio equipment on the market until it has been brought into conformity. Furthermore, where the radio equipment presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the radio equipment 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 its packaging or in a document accompanying the radio equipment. This includes cases where the size of radio equipment does not allow it, or where importers would have to open the packaging in order to indicate their name and address on the radio equipment. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Article 3.

6. When deemed appropriate with regard to the risks presented by radio equipment, importers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the radio equipment presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment 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 10 years after the radio equipment 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 in paper or electronic form necessary to demonstrate the conformity of radio equipment in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market.

Article 13

Obligations of distributors

1. When making radio equipment available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making radio equipment available on the market distributors shall verify that the radio equipment bears the CE marking, that it is accompanied by the documents required by this Directive and by the instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the radio equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 10(2) and (6) to (10) and Article 12(3) respectively.

Where a distributor considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in Article 3, he shall not make the radio equipment available on the market until it has been brought into conformity. Furthermore, where the radio equipment 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 radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Article 3.

4. Distributors who consider or have reason to believe that radio equipment which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the radio equipment presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market 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 in paper or electronic form necessary to demonstrate the conformity of radio equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have made available on the market.

Article 14

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 Directive and he shall be subject to the obligations of the manufacturer under Article 10, where he places radio equipment on the market under his name or trade mark or modifies radio equipment already placed on the market in such a way that compliance with this Directive may be affected.

Article 15

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 radio equipment;

(b) any economic operator to whom they have supplied radio equipment.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the radio equipment and for 10 years after they have supplied the radio equipment.

CHAPTER III

CONFORMITY OF RADIO EQUIPMENT

Article 16

Presumption of conformity of radio equipment

Radio equipment which is 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 set out in Article 3 covered by those standards or parts thereof.

Article 17

Conformity assessment procedures

1. The manufacturer shall perform a conformity assessment of the radio equipment with a view to meeting the essential requirements set out in Article 3. The conformity assessment shall take into account all intended operating conditions and, for the essential requirement set out in point (a) of Article 3(1), the assessment shall also take into account the reasonably foreseeable conditions. Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirements set out in Article 3 in all possible configurations.

2. Manufacturers shall demonstrate compliance of radio equipment with the essential requirements set out in Article 3(1) using any of the following conformity assessment procedures:

(a) internal production control set out in Annex II;

(b) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;

(c) conformity based on full quality assurance set out in Annex IV.

3. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has applied harmonised standards the references of which have been published in the *Official Journal of the European Union*, he shall use any of the following procedures:

(a) internal production control set out in Annex II;

(b) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;

(c) conformity based on full quality assurance set out in Annex IV.

4. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has not applied or has applied only in part harmonised standards the references of which have been published in the *Official Journal of the European Union*, or where such harmonised standards do not exist, radio equipment shall be submitted with regard to those essential requirements to either of the following procedures:

(a) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;

(b) conformity based on full quality assurance set out in Annex IV.

Article 18

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Article 3 has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex VI, shall contain the elements set out in that Annex and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market.

The simplified EU declaration of conformity referred to in Article 10(9) shall contain the elements set out in Annex VII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market. The full text of the EU declaration of conformity shall be available at the internet address referred to in the simplified EU declaration of conformity, in a language or languages required by the Member State in which the radio equipment is placed or made available on the market.

3. Where radio equipment is subject to more than one Union act 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 radio equipment with the requirements laid down in this Directive.

Article 19

General principles of the CE marking

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

2. On account of the nature of radio equipment, the height of the CE marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.

Article 20

Rules and conditions for affixing the CE marking and the identification number of the notified body

1. The CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of radio equipment. The CE marking shall also be affixed visibly and legibly to the packaging.

2. The CE marking shall be affixed before the radio equipment is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex IV is applied.

The identification number of the notified body shall have the same height as the CE marking.

The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.

4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Article 21

Technical documentation

1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the essential requirements set out in Article 3. It shall, at least, contain the elements set out in Annex V.

2. The technical documentation shall be drawn up before radio equipment is placed on the market and shall be continuously updated.

3. The technical documentation and correspondence relating to any EU-type examination procedure shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

4. Where the technical documentation does not comply with paragraphs 1, 2 or 3 of this Article, and in so doing fails to present sufficient relevant data or means used to ensure compliance of radio equipment with the essential requirements set out in Article 3, the market surveillance authority may ask the manufacturer or the importer to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer or the importer within a specified period in order to verify compliance with the essential requirements set out in Article 3.

CHAPTER IV

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 22

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

Article 23

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 28.

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 24. 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

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

Information obligation on 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

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment 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 radio equipment 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 radio equipment 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 radio equipment which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed radio equipment that is necessary for the operations of the conformity assessment body or the use of such radio equipment 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 that radio equipment, 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 III and IV 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 radio equipment 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 radio equipment 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 activities in an appropriate manner.

7. The personnel responsible for carrying out conformity assessment tasks 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 Article 3, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up EU-type examination certificates or quality system approvals, 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 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 III and IV 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, the regulatory activities in the area of radio equipment and frequency planning, and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 27

Presumption of conformity of notified bodies

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

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 III and IV.

Article 29

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 radio equipment 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

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 radio equipment 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 to 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 Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 31

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 bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

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

Article 32

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 restrict, suspend or withdraw notification as appropriate, 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

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.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 45(2).

Article 34

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III and IV.

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 radio equipment 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 radio equipment with this Directive.

3. Where a notified body finds that the essential requirements set out in Article 3 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 an EU-type examination certificate or a quality system approval.

4. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, a notified body finds that radio equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval 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 EU-type examination certificates or quality system approvals, as appropriate.

Article 35

Appeal against decisions of notified bodies

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

Article 36

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Annexes III and IV;

(b) any circumstances affecting the scope of or 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, in accordance with the requirements of Annexes III and IV, provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same categories of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

3. Notified bodies shall fulfil information obligations under Annexes III and IV.

Article 37

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

Coordination of notified bodies

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

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

CHAPTER V

UNION MARKET SURVEILLANCE, CONTROL OF RADIO EQUIPMENT ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 39

Union market surveillance and control of radio equipment entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to radio equipment.

Article 40

Procedure for dealing with radio equipment presenting a risk at national level

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that radio equipment covered by this Directive presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the radio equipment concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the radio equipment does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the radio equipment into compliance with those requirements, to withdraw the radio equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all radio equipment concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the radio equipment being made available on their national market, to withdraw the radio equipment from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant radio equipment, the origin of the radio equipment, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the radio equipment to meet the relevant essential requirements set out in Article 3; or

(b) shortcomings in the harmonised standards referred to in Article 16 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the radio equipment concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the radio equipment from the market, are taken in respect of the radio equipment concerned without delay.

Article 41

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 40(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant radio equipment is withdrawn or recalled from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the radio equipment is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 40(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 42

Compliant radio equipment which presents a risk

1. Where, having carried out an evaluation under Article 40(1), a Member State finds that although radio equipment is in compliance with this Directive, it presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, it shall require the relevant economic operator to take all appropriate measures to ensure that the radio equipment concerned, when placed on the market, no longer presents that risk, to withdraw the radio equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the radio equipment concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the radio equipment concerned, the origin and the supply chain of radio equipment, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 45(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 45(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 43

Formal non-compliance

1. Without prejudice to Article 40, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Directive;

(b) the CE marking has not been affixed;

(c) the identification number of the notified body, where the conformity assessment procedure set out in Annex IV is applied, has been affixed in violation of Article 20 or has not been affixed;

(d) the EU declaration of conformity has not been drawn up;

(e) the EU declaration of conformity has not been drawn up correctly;

(f) technical documentation is either not available or not complete;

(g) the information referred to in Article 10(6) or (7) or Article 12(3) is absent, false or incomplete;

(h) information on the intended use of radio equipment, the EU declaration of conformity or usage restrictions as set out in Article 10(8), (9) and (10) does not accompany the radio equipment;

(i) requirements on identification of economic operators set out in Article 15 are not fulfilled;

(j) Article 5 is not complied with.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit corresponding radio equipment being made available on the market or ensure that it is withdrawn or recalled from the market.

CHAPTER VI

DELEGATED ACTS AND IMPLEMENTING ACTS AND THE COMMITTEE

Article 44

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in the second subparagraph of Articles 3(3), 4(2) and 5(2) shall be conferred on the Commission for a period of five years from 11 June 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in the second subparagraph of Articles 3(3), 4(2) and 5(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to the second subparagraph of Articles 3(3), 4(2) and 5(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 45

Committee procedure

1. The Commission shall be assisted by the Telecommunication Conformity Assessment and Market Surveillance Committee. 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.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

CHAPTER VII

FINAL AND TRANSITIONAL PROVISIONS

Article 46

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive 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.

Article 47

Review and reporting

1. Member States shall submit to the Commission regular reports on the application of this Directive by 12 June 2017 and at least every two years thereafter. The reports shall contain a presentation of the market surveillance activities performed by the Member States and provide information on whether and to what extent compliance with the requirements of this Directive has been attained, including in particular requirements on identification of economic operators.

2. The Commission shall review the operation of this Directive and report thereon to the European Parliament and to the Council, by 12 June 2018 and every five years thereafter. The report shall cover progress on drawing up the relevant standards, as well as any problems that have arisen in the course of implementation. The report shall also outline the activities of the Telecommunication Conformity Assessment and Market Surveillance Committee, assess progress in achieving an open competitive market for radio equipment at Union level and examine how the regulatory framework for the making available on the market and putting into service of radio equipment should be developed in order to achieve the following:

(a) ensure that a coherent system is achieved at Union level for all radio equipment;

(b) allow for convergence of the telecommunications, audiovisual and information technology sectors;

(c) enable regulatory measures to be harmonised at international level;

(d) reach a high level of consumer protection;

(e) ensure that portable radio equipment interworks with accessories, in particular with common chargers;

(f) where radio equipment is fitted with an integral screen, allow the display of the required information on the integral screen.

Article 48

Transitional provisions

Member States shall not impede, for the aspects covered by this Directive, the making available on the market or putting into service of radio equipment covered by this Directive which is in conformity with the relevant Union harmonisation legislation applicable before 13 June 2016 and which was placed on the market before 13 June 2017.

Article 49

Transposition

1. Member States shall adopt and publish, by 12 June 2016, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 13 June 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

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

Article 50

Repeal

Directive 1999/5/EC is repealed with effect from 13 June 2016.

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

Article 51

Entry into force

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

Article 52

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 16 April 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

ANNEX I

EQUIPMENT NOT COVERED BY THIS DIRECTIVE

1. Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations, unless the equipment is made available on the market.

   The following shall be regarded as not being made available on the market:

   (a) radio kits for assembly and use by radio amateurs;

   (b) radio equipment modified by and for the use of radio amateurs;

   (c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.

2. Marine equipment falling within the scope of Council Directive 96/98/EC ([1]).

3. Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council ([2]).

4. Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

([1]) Council Directive 96/98/EC of 20 December 1996 on marine equipment (OJ L 46, 17.2.1997, p. 25).

([2]) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1).

ANNEX II

CONFORMITY ASSESSMENT MODULE A

INTERNAL PRODUCTION CONTROL

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of this Annex, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Article 3.

2. **Technical documentation**

The manufacturer shall establish the technical documentation in accordance with Article 21.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured radio equipment with the technical documentation referred to in point 2 of this Annex and with the relevant essential requirements set out in Article 3.

4. **CE marking and EU declaration of conformity**

4.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX III

CONFORMITY ASSESSMENT MODULES B AND C

EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

When reference is made to this Annex, the conformity assessment procedure shall follow Modules B (EU-type examination) and C (Conformity to type based on internal production control) of this Annex.

Module B

EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.

2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

   The application shall include:

   (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

   (b) a written declaration that the same application has not been lodged with any other notified body;

   (c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;

   (d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type. The EU-type examination certificate may have one or more annexes attached.

   The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control.

   Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

   Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

   Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the *Official Journal of the European Union* have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Module C

Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the radio equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

2. **Manufacturing**

   The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to it.

3. **CE marking and EU declaration of conformity**

3.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

   A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. **Authorised representative**

   The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX IV

CONFORMITY ASSESSMENT MODULE H

CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of this Directive that apply to it.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the radio equipment concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;

(c) the documentation concerning the quality system; and

(d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the radio equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing radio equipment pertaining to the radio equipment type covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. **CE marking and EU declaration of conformity**

5.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each item of radio equipment that satisfies the applicable requirements set out in Article 3.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the national authorities:

(a) the technical documentation referred to in point 3.1;

(b) the documentation concerning the quality system referred to in point 3.1;

(c) the change referred to in point 3.5, as approved;

(d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX V

CONTENTS OF TECHNICAL DOCUMENTATION

The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the radio equipment including:

  (i) photographs or illustrations showing external features, marking and internal layout;

  (ii) versions of software or firmware affecting compliance with essential requirements;

  (iii) user information and installation instructions;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) copy of the EU declaration of conformity;

(f) where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;

(g) results of design calculations made, examinations carried out, and other relevant similar elements;

(h) test reports;

(i) an explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10).

ANNEX VI

EU DECLARATION OF CONFORMITY (No XXX) [1]

1. Radio equipment (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the radio equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the radio equipment):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

   Directive 2014/53/EU

   Other Union harmonisation legislation where applicable
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification number and version and, where applicable, date of issue:
7. Where applicable, the notified body … (name, number) … performed … (description of intervention) … and issued the EU-type examination certificate: …
8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:
9. Additional information:

   Signed for and on behalf of: …

   (place and date of issue):

   (name, function) (signature):

[1] It is optional for the manufacturer to assign a number to the EU declaration of conformity.

ANNEX VII

SIMPLIFIED EU DECLARATION OF CONFORMITY

The simplified EU declaration of conformity referred to in Article 10(9) shall be provided as follows:

Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:

ANNEX VIII

CORRELATION TABLE

Directive 1999/5/EC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3(1) and (2)	Article 3(1) and (2)
Article 3(3) and Article 15a	Article 3(3), with the exception of Article 3(3)(i), and Article 44
Article 4(1) and Articles 13 to 15	Articles 8 and 45
Article 4(2)	—
Article 5(1)	Article 16
Article 5(2) and (3)	—
Article 6(1)	Article 6
Article 6(2)	—
Article 6(3)	Article 10(8), (9) and (10)
Article 6(4)	—
Article 7(1) and (2)	Article 7
Article 7(3), (4) and (5)	—
Article 8(1) and (2)	Article 9
Article 8(3)	—
Article 9	Articles 39 to 43
Article 10	Article 17
Article 11	Articles 22 to 38
Article 12	Articles 19 and 20 and Article 10(6) and (7)
Article 16	—
Article 17	Article 47
Article 18	Article 48
Article 19	Article 49
Article 20	Article 50
Article 21	Article 51
Article 22	Article 52
Annex I	Annex I
Annex II	Annex II
Annex III	—
Annex IV	Annex III
Annex V	Annex IV
Annex VI	Article 26
Annex VII(1) to (4)	Articles 19 and 20
Annex VII(5)	Article 10(10)

STATEMENT OF THE EUROPEAN PARLIAMENT

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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