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I

(Legislative acts)

DIRECTIVES

DIRECTIVE 2011/61/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 8 June 2011****on Alternative Investment Fund Managers and amending Directives 2003/41/EC and 2009/65/EC and Regulations (EC) No 1060/2009 and (EU) No 1095/2010****(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 53(1) thereof,

Having regard to the proposal from the European Commission,

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) Managers of alternative investment funds (AIFMs) are responsible for the management of a significant amount of invested assets in the Union, account for significant amounts of trading in markets for financial instruments, and can exercise an important influence on markets and companies in which they invest.
- (2) The impact of AIFMs on the markets in which they operate is largely beneficial, but recent financial difficulties have underlined how the activities of AIFMs may also serve to spread or amplify risks through the financial system. Uncoordinated national responses make the efficient management of those risks difficult. This

Directive therefore aims at establishing common requirements governing the authorisation and supervision of AIFMs in order to provide a coherent approach to the related risks and their impact on investors and markets in the Union.

- (3) Recent difficulties in financial markets have underlined that many AIFM strategies are vulnerable to some or several important risks in relation to investors, other market participants and markets. In order to provide comprehensive and common arrangements for supervision, it is necessary to establish a framework capable of addressing those risks taking into account the diverse range of investment strategies and techniques employed by AIFMs. Consequently, this Directive should apply to AIFMs managing all types of funds that are not covered by Directive 2009/65/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of laws, regulations and administrative provisions relating to the undertakings for collective investment in transferable securities (UCITS) ⁽⁴⁾, irrespective of the legal or contractual manner in which the AIFMs are entrusted with this responsibility. AIFMs should not be entitled to manage UCITS within the meaning of Directive 2009/65/EC on the basis of an authorisation under this Directive.

- (4) This Directive aims to provide for an internal market for AIFMs and a harmonised and stringent regulatory and supervisory framework for the activities within the Union of all AIFMs, including those which have their registered office in a Member State (EU AIFMs) and those which have their registered office in a third country (non-EU AIFMs). As the practical consequences and possible difficulties resulting from a harmonised regulatory framework and an internal market for non-EU AIFMs performing management and/or marketing activities within the Union and EU AIFMs managing non-EU alternative investment funds (AIFs), are

⁽¹⁾ OJ C 272, 13.11.2009, p. 1.

⁽²⁾ OJ C 18, 19.1.2011, p. 90.

⁽³⁾ Position of the European Parliament of 11 November 2010 (not yet published in the Official Journal) and decision of the Council of 27 May 2011.

⁽⁴⁾ OJ L 302, 17.11.2009, p. 32.

uncertain and difficult to predict due to the lack of previous experience in this regard, a review mechanism should be provided for. It is intended that, after a transitional period of 2 years, a harmonised passport regime become applicable to non-EU AIFMs performing management and/or marketing activities within the Union and EU AIFMs managing non-EU AIFs after the entry into force of a delegated act by the Commission in this regard. It is intended that the harmonised regime, during a further transitional period of 3 years, co-exist with the national regimes of the Member States subject to certain minimum harmonised conditions. After that 3-year period of co-existence, it is intended that the national regimes be brought to an end on the entry into force of a further delegated act by the Commission.

- (5) 4 years after the deadline for transposition of this Directive, the Commission should review the application and the scope of this Directive taking into account its objectives and should assess whether or not the Union harmonised approach has caused any ongoing major market disruption and whether or not this Directive functions effectively in light of the principles of the internal market and of a level playing field.
- (6) The scope of this Directive should be limited to entities managing AIFs as a regular business – regardless of whether the AIF is of an open-ended or a closed-ended type, whatever the legal form of the AIF, and whether or not the AIF is listed – which raise capital from a number of investors with a view to investing that capital for the benefit of those investors in accordance with a defined investment policy.
- (7) Investment undertakings, such as family office vehicles which invest the private wealth of investors without raising external capital, should not be considered to be AIFs in accordance with this Directive.
- (8) The entities not considered to be AIFMs pursuant to this Directive fall outside its scope. As a consequence, this Directive should not apply to holding companies as defined herein. However, managers of private equity funds or AIFMs managing AIFs whose shares are admitted to trading on a regulated market should not be excluded from its scope. Further, this Directive should not apply to the management of pension funds; employee participation or savings schemes; supranational institutions; national central banks; national, regional and local governments and bodies or institutions which manage funds supporting social security and pension systems; securitisation special purpose entities; or insurance contracts and joint ventures.
- (9) Investment firms authorised under Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments⁽¹⁾ and credit institutions authorised under Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions⁽²⁾ should not be required to obtain an authorisation under this Directive in order to provide investment services such as individual portfolio management in respect of AIFs. However, investment firms should be able, directly or indirectly, to offer units or shares of an AIF to, or place such units or shares with, investors in the Union only to the extent that the units or shares can be marketed in accordance with this Directive. When transposing this Directive into national law, the Member States should take into account the regulatory purpose of that requirement and should ensure that investment firms established in a third country that, pursuant to the relevant national law, can provide investment services in respect of AIFs also fall within the scope of that requirement. The provision of investment services by those entities in respect of AIFs should never amount to a de facto circumvention of this Directive by means of turning the AIFM into a letter-box entity, irrespective of whether the AIFM is established in the Union or in a third country.
- (10) This Directive does not regulate AIFs. AIFs should therefore be able to continue to be regulated and supervised at national level. It would be disproportionate to regulate the structure or composition of the portfolios of AIFs managed by AIFMs at Union level and it would be difficult to provide for such extensive harmonisation due to the very diverse types of AIFs managed by AIFMs. This Directive therefore does not prevent Member States from adopting or from continuing to apply national requirements in respect of AIFs established in their territory. The fact that a Member State may impose requirements additional to those applicable in other Member States on AIFs established in its territory should not prevent the exercise of rights of AIFMs authorised in accordance with this Directive in other Member States to market to professional investors in the Union certain AIFs established outside the Member State imposing additional requirements and which are therefore not subject to and do not need to comply with those additional requirements.
- (11) Several provisions of this Directive require AIFMs to ensure compliance with requirements for which, in some fund structures, AIFMs are not responsible. An example of such fund structures is where the responsibility for appointing the depositary rests with the AIF or another entity acting on behalf of the AIF. In such cases, the AIFM has no ultimate control over whether a depositary is in fact appointed unless the AIF is internally

⁽¹⁾ OJ L 145, 30.4.2004, p. 1.

⁽²⁾ OJ L 177, 30.6.2006, p. 1.

managed. Since this Directive does not regulate AIFs, it cannot require an AIF to appoint a depository. In cases of failure of an AIFM to ensure compliance with the applicable requirements of an AIF or another entity on its behalf, the competent authorities should require the AIFM to take the necessary steps to remedy the situation. If, despite such steps, the non-compliance persists, and in so far as it concerns an EU AIFM or an authorised non-EU AIFM managing an EU AIF, the AIFM should resign as manager of that AIF. If the AIFM fails to resign, the competent authorities of its home Member State should require such resignation and the marketing in the Union of the AIF concerned should no longer be permitted. The same prohibition should apply to authorised non-EU AIFMs marketing non-EU AIFs in the Union.

- (12) Unless specifically provided for otherwise, where this Directive refers to the interests of the investors of an AIF the investors' interests in their specific capacity as investors of the AIF, and not their individual interests, are envisaged.
- (13) Subject to the exceptions and restrictions provided for, this Directive should be applicable to all EU AIFMs managing EU AIFs or non-EU AIFs, irrespective of whether or not they are marketed in the Union, to non-EU AIFMs managing EU AIFs, irrespective of whether or not they are marketed in the Union, and to non-EU AIFMs marketing EU AIFs or non-EU AIFs in the Union.
- (14) This Directive lays down requirements regarding the manner in which AIFMs should manage AIFs under their responsibility. For non-EU AIFMs this is limited to the management of EU AIFs and other AIFs the units or shares of which are also marketed to professional investors in the Union.
- (15) The authorisation of EU AIFMs in accordance with this Directive covers the management of EU AIFs established in the home Member State of the AIFM. Subject to further notification requirements, this also includes the marketing to professional investors within the Union of EU AIFs managed by the EU AIFM and the management of EU AIFs established in Member States other than the home Member State of the AIFM. This Directive also provides for the conditions subject to which authorised EU AIFMs are entitled to market non-EU AIFs to professional investors in the Union and the conditions subject to which a non-EU AIFM can obtain an authorisation to manage EU AIFs and/or to market AIFs to professional investors in the Union with a passport. During a period that is intended to be transitional, Member States should also be able to allow EU AIFMs to market non-EU AIFs in their territory only and/or to allow non-EU AIFMs to

manage EU AIFs, and/or market AIFs to professional investors, in their territory only, subject to national law, in so far as certain minimum conditions pursuant to this Directive are met.

- (16) This Directive should not apply to AIFMs in so far as they manage AIFs whose only investors are the AIFMs themselves or their parent undertakings, their subsidiaries or other subsidiaries of their parent undertaking and where those investors are not themselves AIFs.
- (17) This Directive further provides for a lighter regime for AIFMs where the cumulative AIFs under management fall below a threshold of EUR 100 million and for AIFMs that manage only unleveraged AIFs that do not grant investors redemption rights during a period of 5 years where the cumulative AIFs under management fall below a threshold of EUR 500 million. Although the activities of the AIFMs concerned are unlikely to have individually significant consequences for financial stability, it is possible that aggregation causes their activities to give rise to systemic risks. Consequently, those AIFMs should not be subject to full authorisation but to registration in their home Member States and should, *inter alia*, provide their competent authorities with relevant information regarding the main instruments in which they are trading and on the principal exposures and most important concentrations of the AIFs they manage. However, in order to be able to benefit from the rights granted under this Directive, those smaller AIFMs should be allowed to be treated as AIFMs subject to the opt-in procedure provided for by this Directive. That exemption should not limit the ability of Member States to impose stricter requirements on those AIFMs that have not opted in.
- (18) No EU AIFM should be able to manage and/or market EU AIFs to professional investors in the Union unless it has been authorised in accordance with this Directive. An AIFM authorised in accordance with this Directive should meet the conditions for authorisation established in this Directive at all times.
- (19) As soon as this is permitted under this Directive, a non-EU AIFM intending to manage EU AIFs and/or market AIFs in the Union with a passport or an EU AIFM intending to market non-EU AIFs in the Union with a passport should also be authorised in accordance with this Directive. At least during a transitional period, a Member State should also be able to allow a non-EU AIFM to market AIFs in that Member State and to authorise an EU AIFM to market non-EU AIFs in that Member State in so far as the minimum conditions set out in this Directive are met.

- (20) Depending on their legal form, it should be possible for AIFs to be either externally or internally managed. AIFs should be deemed internally managed when the management functions are performed by the governing body or any other internal resource of the AIF. Where the legal form of the AIF permits internal management and where the AIF's governing body chooses not to appoint an external AIFM, the AIF is also AIFM and should therefore comply with all requirements for AIFMs under this Directive and be authorised as such. An AIFM which is an internally managed AIF should however not be authorised as the external manager of other AIFs. An AIF should be deemed externally managed when an external legal person has been appointed as manager by or on behalf of the AIF, which through such appointment is responsible for managing the AIF. Where an external AIFM has been appointed to manage a particular AIF, that AIFM should not be deemed to be providing the investment service of portfolio management as defined in point (9) of Article 4(1) of Directive 2004/39/EC, but, rather, collective portfolio management in accordance with this Directive.
- (21) Management of AIFs should mean providing at least investment management services. The single AIFM to be appointed pursuant to this Directive should never be authorised to provide portfolio management without also providing risk management or vice versa. Subject to the conditions set out in this Directive, an authorised AIFM should not, however, be prevented from also engaging in the activities of administration and marketing of an AIF or from engaging in activities related to the assets of the AIF. An external AIFM should not be prevented from also providing the service of management of portfolios of investments with mandates given by investors on a discretionary, client-by-client basis, including portfolios owned by pension funds and institutions for occupational retirement provision which are covered by 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⁽¹⁾, or from providing the non-core services of investment advice, safe-keeping and administration in relation to units of collective investment undertakings and reception and transmission of orders. Pursuant to authorisation under Directive 2009/65/EC, an external AIFM should be allowed to manage UCITS.
- (22) It is necessary to ensure that AIFMs operate subject to robust governance controls. AIFMs should be managed and organised so as to minimise conflicts of interest. The organisational requirements established under this Directive should be without prejudice to systems and controls established by national law for the registration of persons working within or for an AIFM.
- (23) It is necessary to provide for the application of minimum capital requirements to ensure the continuity and the regularity of the management of AIFs provided by an AIFM and to cover the potential exposure of AIFMs to professional liability in respect of all their activities, including the management of AIFs under a delegated mandate. AIFMs should be free to choose whether to cover potential risks of professional liability by additional own funds or by an appropriate professional indemnity insurance.
- (24) In order to address the potentially detrimental effect of poorly designed remuneration structures on the sound management of risk and control of risk-taking behaviour by individuals, there should be an express obligation for AIFMs to establish and maintain, for those categories of staff whose professional activities have a material impact on the risk profiles of AIFs they manage, remuneration policies and practices that are consistent with sound and effective risk management. Those categories of staff should at least include senior management, risk takers, control functions, and any employees receiving total remuneration that takes them into the same remuneration bracket as senior management and risk takers.
- (25) The principles governing remuneration policies should recognise that AIFMs are able to apply those policies in different ways according to their size and the size of the AIFs they manage, their internal organisation and the nature, the scope and the complexity of their activities.
- (26) The principles regarding sound remuneration policies set out in the Commission Recommendation 2009/384/EC of 30 April 2009 on remuneration policies in the financial services sector⁽²⁾ are consistent with and complement the principles of this Directive.
- (27) In order to promote supervisory convergences in the assessment of remuneration policies and practices, the European Supervisory Authority (European Securities and Markets Authority), established by Regulation (EU) No 1095/2010 of the European Parliament and of the Council⁽³⁾ (ESMA) should ensure the existence of guidelines on sound remuneration policies in the AIFM sector. The European Supervisory Authority (European Banking Authority) established by Regulation (EU) No 1093/2010 of the European Parliament and of the Council⁽⁴⁾ should assist it in the elaboration of such guidelines.

⁽¹⁾ OJ L 235, 23.9.2003, p. 10.

⁽²⁾ OJ L 120, 15.5.2009, p. 22.

⁽³⁾ OJ L 331, 15.12.2010, p. 84.

⁽⁴⁾ OJ L 331, 15.12.2010, p. 12.

- (28) The provisions on remuneration should be without prejudice to the full exercise of fundamental rights guaranteed by the Treaties, in particular Article 153(5) TFEU, general principles of national contract and labour law, applicable legislation regarding shareholders' rights and involvement and the general responsibilities of the administrative and supervisory bodies of the institution concerned, as well as the right, where applicable, of social partners to conclude and enforce collective agreements, in accordance with national laws and traditions.
- (29) Reliable and objective asset valuation is crucial for the protection of investor interests. AIFMs employ different methodologies and systems for valuing assets, depending on the assets and markets in which they predominantly invest. It is appropriate to recognise those differences but, nevertheless, to require in all cases AIFMs to implement valuation procedures resulting in the proper valuation of assets of AIFs. The process for valuation of assets and calculation of the net asset value should be functionally independent from the portfolio management and the remuneration policy of the AIFM and other measures should ensure that conflicts of interest are prevented and that undue influence on the employees is prevented. Subject to certain conditions, AIFMs should be able to appoint an external valuer to perform the valuation function.
- (30) Subject to strict limitations and requirements, including the existence of objective reasons, an AIFM should be able to delegate the carrying out of some of its functions on its behalf in accordance with this Directive so as to increase the efficiency of the conduct of its business. Subject to the same conditions, sub-delegation should also be allowed. AIFMs should, however, remain responsible for the proper performance of the delegated functions and compliance with this Directive at all times.
- (31) The strict limitations and requirements set out on the delegation of tasks by AIFMs should apply to the delegation of management functions set out in Annex I. Delegation of supporting tasks, such as administrative or technical functions performed by the AIFM as a part of its management tasks, should not be subject to the specific limitations and requirements set out in this Directive.
- (32) Recent developments underline the crucial need to separate asset safe-keeping and management functions, and to segregate investor assets from those of the manager. Although AIFMs manage AIFs with different business models and arrangements for, inter alia, asset safe-keeping, it is essential that a depositary separate from the AIFM is appointed to exercise depositary functions with respect to AIFs.
- (33) The provisions of this Directive relating to the appointment and the tasks of a depositary should apply to all AIFs managed by an AIFM subject to this Directive and therefore to all AIF business models. They should, however, be adapted to the specificities of different business models. For some business models certain depositary tasks are more relevant than for others, depending on the type of assets the AIFs are investing in and the tasks related to those assets.
- (34) For AIFs that have no redemption rights exercisable during the period of 5 years from the date of the initial investments and that, in accordance with their core investment policy, generally do not invest in assets that must be held in custody in accordance with this Directive or generally invest in issuers or non-listed companies in order potentially to acquire control over such companies in accordance with this Directive, such as private equity, venture capital funds and real estate funds, Member States should be able to allow a notary, a lawyer, a registrar or another entity to be appointed to carry out depositary functions. In such cases the depositary functions should be part of professional or business activities in respect of which the appointed entity is subject to mandatory professional registration recognised by law or to legal or regulatory provisions or rules of professional conduct and can provide sufficient financial and professional guarantees to enable it to perform effectively the relevant depositary functions and meet the commitments inherent in those functions. This takes account of current practice for certain types of closed-ended funds. However, for all other AIFs, the depositary should be a credit institution, an investment firm or another entity permitted under Directive 2009/65/EC, given the importance of the custody function. For non-EU AIFs only, it should also be possible for the depositary to be a credit institution or any other entity of the same nature as the entities referred to in this recital as long as it is subject to effective prudential regulation and supervision which have the same effect as Union law and are effectively enforced.
- (35) The depositary should have its registered office or a branch in the same country as the AIF. It should be possible for a non-EU AIF to have a depositary established in the relevant third country only if certain additional conditions are met. On the basis of the criteria set out in delegated acts, the Commission should be empowered to adopt implementing measures, stating that prudential regulation and supervision of a third country have the same effect as Union law and are effectively enforced. Further, the mediation procedure set out in Article 19 of Regulation (EU) No 1095/2010 should apply in the event that competent authorities disagree on the correct application of the other additional conditions. Alternatively, for non-EU AIFs, the depositary should also be able to be established in the home Member State or in the Member State of reference of the AIFM managing the AIF.

- (36) The Commission is invited to examine the possibilities of putting forward an appropriate horizontal legislative proposal that clarifies the responsibilities and liabilities of a depositary and governs the right of a depositary in one Member State to provide its services in another Member State.
- (37) The depositary should be responsible for the proper monitoring of the AIF's cash flows, and, in particular, for ensuring that investor money and cash belonging to the AIF, or to the AIFM acting on behalf of the AIF, is booked correctly on accounts opened in the name of the AIF or in the name of the AIFM acting on behalf of the AIF or in the name of the depositary acting on behalf of the AIF for the safe-keeping of the assets of the AIF, including the holding in custody of financial instruments that can be registered in a financial instruments account opened in the depositary's books and all financial instruments that can be physically delivered to the depositary, and for the verification of ownership of all other assets by the AIF or the AIFM on behalf of the AIF. When ensuring investor money is booked in cash accounts, the depositary should take into account the principles set out in Article 16 of Commission Directive 2006/73/EC of 10 August 2006 implementing Directive 2004/39/EC of the European Parliament and of the Council as regards organisational requirements and operating conditions for investment firms and defined terms for the purposes of that Directive ⁽¹⁾.
- (38) A depositary should act honestly, fairly, professionally, independently and in the interest of the AIF or of the investors of the AIF.
- (39) It should be possible for a depositary to delegate the safe-keeping of assets to a third party which, in its turn, should be able to delegate that function. However, delegation and sub-delegation should be objectively justified and subject to strict requirements in relation to the suitability of the third party entrusted with the delegated function, and in relation to the due skill, care and diligence that the depositary should employ to select, appoint and review that third party.
- (40) A third party to whom the safe-keeping of assets is delegated should be able to maintain a common segregated account for multiple AIFs, a so-called 'omnibus account'.
- (41) Entrusting the custody of assets to the operator of a securities settlement system as designated for the purposes of Directive 98/26/EC of the European Parliament and of the Council of 19 May 1998 on settlement finality in payment and securities settlement systems ⁽²⁾ or entrusting the provision of similar services to third-country securities settlement systems should not be considered to be a delegation of custody functions.
- (42) The strict limitations and requirements to which the delegation of tasks by the depositary is subject should apply to the delegation of its specific functions as a depositary, namely the monitoring of the cash flow, the safe-keeping of assets and the oversight functions. Delegation of supporting tasks that are linked to its depositary tasks, such as administrative or technical functions performed by the depositary as a part of its depositary tasks, is not subject to the specific limitations and requirements set out in this Directive.
- (43) This Directive also takes account of the fact that many AIFs, and in particular hedge funds, currently make use of a prime broker. This Directive ensures that AIFs may continue to use the function of prime brokers. However, unless it has functionally and hierarchically separated the performance of its depositary functions from its tasks as prime broker and the potential conflicts of interest are properly identified, managed and disclosed to the investors of the AIF, no prime broker should be appointed as a depositary, since prime brokers act as counterparties to AIFs and therefore cannot at the same time act in the best interest of the AIF as is required of a depositary. Depositaries should be able to delegate custody tasks to one or more prime brokers or other third parties. In addition to the delegated custody tasks prime brokers should be allowed to provide prime brokerage services to the AIF. Those prime brokerage services should not form part of the delegation arrangement.
- (44) The depositary should be liable for the losses suffered by the AIFM, the AIF and the investors. This Directive distinguishes between the loss of financial instruments held in custody, and any other losses. In the case of a loss other than of financial instruments held in custody, the depositary should be liable in the case of intent or negligence. Where the depositary holds assets in custody and those assets are lost, the depositary should be liable, unless it can prove that the loss is the result of an external event beyond its reasonable control, the consequences of which would have been unavoidable despite all reasonable efforts to the contrary. In this context, a depositary should not, for example, be able to rely on internal situations such as a fraudulent act by an employee to discharge itself of liability.
- (45) Where the depositary delegates custody tasks and the financial instruments held in custody by a third party are lost, the depositary should be liable. However, provided that the depositary is expressly allowed to discharge itself of liability subject to a contractual

⁽¹⁾ OJ L 241, 2.9.2006, p. 26.

⁽²⁾ OJ L 166, 11.6.1998, p. 45.

transfer of such liability to that third party, pursuant to a written contract between the depositary and the AIF or the AIFM acting on behalf of the AIF, in which such a discharge is objectively justified, and that the third party can be held liable for the loss based on a contract between the depositary and the third party, the depositary should be able to discharge itself of liability if it can prove that it has exercised due skill, care and diligence and that the specific requirements for delegation are met. By imposing the requirement of a contractual transfer of liability to the third party, this Directive intends to attach external effects to such contract, making the third party directly liable to the AIF, or to the investors of the AIF, for the loss of the financial instruments held in custody.

- (46) Further, where the law of a third country requires that certain financial instruments be held in custody by a local entity and there are no local entities that satisfy all depositary delegation requirements, the depositary should be able to discharge itself of liability provided that: the rules or instruments of incorporation of the AIF concerned expressly allow for such a discharge; the investors have been duly informed of that discharge and the circumstances justifying the discharge prior to their investment; the AIF or the AIFM on behalf of the AIF instructed the depositary to delegate the custody of such financial instruments to a local entity; there is a written contract between the depositary and the AIF or the AIFM acting on behalf of the AIF, which expressly allows such a discharge; and there is a written contract between the depositary and the third party which expressly transfers the liability of the depositary to that third party and makes it possible for the AIF, or the AIFM acting on behalf of the AIF, to make a claim against the third party in respect of the loss of financial instruments or for the depositary to make such a claim on their behalf.
- (47) This Directive should be without prejudice to any future legislative measures with respect to the depositary in Directive 2009/65/EC, because UCITS and AIFs are different both in the investment strategies they follow and in the type of investors for which they are intended.
- (48) An AIFM should, for each of the EU AIFs it manages and for each of the AIFs it markets in the Union, make available an annual report for each financial year no later than 6 months following the end of the financial year in accordance with this Directive. That 6-month period should be without prejudice to the right of the Member States to impose a shorter period.
- (49) Given that it is possible for an AIFM to employ leverage and, under certain conditions, to contribute to the build up of systemic risk or disorderly markets, special requirements should be imposed on AIFMs employing leverage. The information needed to detect, monitor

and respond to those risks has not been collected in a consistent way throughout the Union, and shared across Member States so as to identify potential sources of risk to the stability of financial markets in the Union. To remedy that situation, special requirements should apply to AIFMs which employ leverage on a substantial basis at the level of the AIF. Such AIFMs should be required to disclose information regarding the overall level of leverage employed, the leverage arising from borrowing of cash or securities and the leverage arising from positions held in derivatives, the reuse of assets and the main sources of leverage in their AIFs. Information gathered by competent authorities should be shared with other authorities in the Union, with ESMA and with the European Systemic Risk Board (ESRB) established by 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⁽¹⁾ so as to facilitate a collective analysis of the impact of the leverage of AIFs managed by AIFMs on the financial system in the Union, as well as a common response. If one or more AIFs managed by an AIFM could potentially constitute an important source of counterparty risk to a credit institution or other systemically relevant institutions in other Member States, such information should also be shared with the relevant authorities.

- (50) In order to ensure a proper assessment of the risks induced by the use of leverage by an AIFM with respect to the AIFs it manages, the AIFM should demonstrate that the leverage limits for each AIF it manages are reasonable and that it complies with those limits at all times. Where the stability and integrity of the financial system may be threatened, the competent authorities of the home Member State of the AIFM should be able to impose limits to the level of leverage that an AIFM can employ in AIFs under its management. ESMA and the ESRB should be informed about any actions taken in this respect.
- (51) It is also considered necessary to allow ESMA, after taking into account the advice of the ESRB, to determine that the leverage used by an AIFM or by a group of AIFMs poses a substantial risk to the stability and the integrity of the financial system and to issue advice to competent authorities specifying the remedial measures to be taken.
- (52) It is necessary to ensure that the competent authorities of the home Member State of the AIFM, the companies over which AIFs managed by an AIFM exercise control and the employees of such companies receive certain information necessary for those companies to assess how that control will impact their situation.

⁽¹⁾ OJ L 331, 15.12.2010, p. 1.

- (53) Where AIFMs manage AIFs which exercise control over an issuer whose shares are admitted to trading on a regulated market, information should generally be disclosed in accordance with Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004 on takeover bids⁽¹⁾ and Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market⁽²⁾. Specific requirements should apply to AIFMs managing AIFs which exercise control over a non-listed company. In order to ensure transparency regarding the controlled company, enhanced transparency, disclosure and reporting requirements should apply. Further, the annual reports of the relevant AIF should be supplemented with regard to the controlled company or such additional information should be included in the annual report of the controlled company. Such information should be made available to the employees' representatives or, where there are none, the employees themselves, and to the investors of the relevant AIF.
- (54) Specific information requirements towards employees of certain companies apply in cases where AIFs acquire control over such companies in accordance with this Directive. However, in most cases the AIFM has no control over the AIF, unless it is an internally managed AIF. Furthermore, there is, in accordance with the general principles of company law, no direct relationship between the shareholders and the employees' representatives or, where there are none, the employees themselves. For those reasons, no direct information requirements towards the employees' representatives or, where there are none, the employees themselves, can be imposed pursuant to this Directive on a shareholder or its manager, namely the AIF and the AIFM. As regards the information requirements towards such employees' representatives or, where there are none, the employees themselves, this Directive should provide for an obligation on the AIFM concerned to use its best efforts to ensure that the board of directors of the company concerned discloses the relevant information to the employees' representatives or, where there are none, the employees themselves.
- (55) The Commission is invited to examine the need and the possibilities to amend the information and disclosure requirements applicable in cases of control over non-listed companies or issuers set out in this Directive on a general level, regardless of the type of investor.
- (56) Where an AIFM manages one or more AIFs which acquire control over a non-listed company, the AIFM should provide the competent authorities of its home Member State with information on the financing of the acquisition. That obligation to provide information on financing should also apply when an AIFM manages AIFs which acquire control over an issuer of shares admitted to trading on a regulated market.
- (57) Where an AIFM manages one or more AIFs which acquire control over a non-listed company or an issuer, the AIFM should, for a period of 24 months following the acquisition of control of the company by the AIFs, first, not be allowed to facilitate, support or instruct any distribution, capital reduction, share redemption and/or acquisition of own shares by the company in accordance with this Directive; second, in so far as the AIFM is authorised to vote on behalf of the AIFs at the meetings of governing bodies of the company, not vote in favour of a distribution, capital reduction, share redemption and/or acquisition of own shares by the company in accordance with this Directive; and third, in any event, use its best efforts to prevent distributions, capital reductions, share redemptions and/or the acquisition of own shares by the company in accordance with this Directive. When transposing this Directive into national law, the Member States should take into account the regulatory purpose of the provisions of Section 2 of Chapter V of this Directive and take due account in this context of the need for a level playing field between EU AIFs and non-EU AIFs when acquiring control in companies established in the Union.
- (58) The notification and disclosure requirements and the specific safeguards against asset stripping in the case of control over a non-listed company or an issuer should be subject to a general exception for control over small and medium-sized enterprises and special purpose vehicles with the purpose of purchasing, holding or administering real estate. Further, those requirements do not aim at making public proprietary information which would put the AIFM at a disadvantage vis-à-vis potential competitors such as sovereign wealth funds or competitors that may want to put the target company out of business by using the information to their advantage. The obligations to notify and disclose information should therefore apply subject to the conditions and restrictions relating to confidential information set out in Directive 2002/14/EC of the European Parliament and of the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community⁽³⁾ and without prejudice to Directives 2004/25/EC and 2004/109/EC. This means that Member States should provide that within the limits and conditions laid down by national law the employees' representatives, and anyone assisting them, are not authorised to reveal to employees and to third parties any information affecting the legitimate interests of the company that has expressly been provided to them in

⁽¹⁾ OJ L 142, 30.4.2004, p. 12.

⁽²⁾ OJ L 390, 31.12.2004, p. 38.

⁽³⁾ OJ L 80, 23.3.2002, p. 29.

confidence. Member States should, however, be able to authorise the employees' representatives and anyone assisting them to pass on confidential information to employees and to third parties bound by an obligation of confidentiality. Member States should provide that the relevant AIFMs do not request the communication of information by the board of directors to the employees' representatives or, where there are none, the employees themselves, when the nature of that information is such that, according to objective criteria, it would seriously harm the functioning of the company concerned or would be prejudicial to it. The notification and disclosure requirements and the specific safeguards against asset stripping should also apply without prejudice to any stricter rules adopted by Member States.

(59) This Directive also lays down the conditions subject to which EU AIFMs may market the units or shares of EU AIFs to professional investors in the Union. Such marketing by EU AIFMs should be allowed only in so far as the AIFM complies with this Directive and the marketing occurs with a passport, without prejudice to the marketing of AIFs by AIFMs falling below the thresholds provided for in this Directive. It should be possible for Member States to allow marketing of AIFs by AIFMs falling below those thresholds subject to national provisions.

(60) It should be possible for units or shares of an AIF to be listed on a regulated market in the Union, or offered or placed by third parties acting on behalf of the AIFM, in a particular Member State only if the AIFM which manages the AIF is itself permitted to market the units or shares of the AIF in that Member State. In addition, other national and Union law, such as Directive 2003/71/EC of the European Parliament and of the Council of 4 November 2003 on the prospectus to be published when securities are offered to the public or admitted to trading⁽¹⁾ and Directive 2004/39/EC, may also regulate the distribution of AIFs to investors in the Union.

(61) Many EU AIFMs currently manage non-EU AIFs. It is appropriate to allow authorised EU AIFMs to manage non-EU AIFs without marketing them in the Union without imposing on them the strict depositary requirements and the requirements relating to the annual report provided for in this Directive, as those requirements have been included for the protection of Union investors.

(62) After the entry into force of a delegated act adopted by the Commission in this regard, which will, in principle, taking into account the advice provided by ESMA, occur

2 years after the deadline for transposition of this Directive, authorised EU AIFMs intending to market non-EU AIFs to professional investors in their home Member State and/or in other Member States should be allowed to do so with a passport in so far as they comply with this Directive. That right should be subject to notification procedures and conditions in relation to the third country of the non-EU AIF.

(63) During a transitional period, which will, in principle, taking into account ESMA's advice, be brought to an end by means of a delegated act 3 years after the establishment of the passport for non-EU AIFMs, EU AIFMs intending to market non-EU AIFs in certain Member States, but without a passport, should also be permitted to do so by the relevant Member States, but only in so far as they comply with this Directive with the exception of the depositary requirements. Such EU AIFMs should, however, ensure that one or more entities are appointed to carry out the duties of the depositary. In addition, appropriate cooperation arrangements for the purpose of systemic risk oversight and in line with international standards should be in place between the competent authorities of the home Member State of the AIFM and the supervisory authorities of the third country where the non-EU AIF is established in order to ensure an efficient exchange of information that allows the competent authorities of the home Member State of the AIFM to carry out their duties in accordance with this Directive. The cooperation arrangements should not be used as a barrier to impede non-EU AIFs from being marketed in a Member State. Further, the third country where the non-EU AIF is established should not be listed as a Non-Cooperative Country and Territory by the Financial Action Task Force on anti-money laundering and terrorist financing (FATF).

(64) After the entry into force of a delegated act adopted by the Commission in that regard, which will, in principle, taking into account advice given by ESMA, occur 2 years after the deadline for transposition of this Directive, a basic principle of this Directive should be that a non-EU AIFM is to benefit from the rights conferred under this Directive, such as to market units or shares of AIFs throughout the Union with a passport, subject to its compliance with this Directive. This should ensure a level playing field between EU and non-EU AIFMs. This Directive therefore provides for an authorisation applicable to non-EU AIFMs which will become applicable after the entry into force of the delegated act adopted by the Commission in this regard. To ensure that such compliance is enforced, the competent authorities of a Member State should enforce compliance with this Directive. For such non-EU AIFMs the competent supervisory authorities should be the competent authorities of the Member State of reference, as defined in this Directive.

⁽¹⁾ OJ L 345, 31.12.2003, p. 64.

- (65) Therefore, where a non-EU AIFM intends to manage EU AIFs and/or market AIFs in the Union with a passport, it should also be required to comply with this Directive, so that it is subject to the same obligations as EU AIFMs. In very exceptional circumstances, if and to the extent compliance with a provision of this Directive is incompatible with compliance with the law to which the non-EU AIFM or the non-EU AIF marketed in the Union is subject, it should be possible for the non-EU AIFM to be exempted from compliance with the relevant provision of this Directive if it can demonstrate that: it is impossible to combine compliance with a provision of this Directive with compliance with a mandatory provision in the law to which the non-EU AIFM or the non-EU AIF marketed in the Union is subject; the law to which the non-EU AIFM or the non-EU AIF is subject provides for an equivalent rule having the same regulatory purpose and offering the same level of protection to the investors of the relevant AIF; and the non-EU AIFM or the non-EU AIF complies with that equivalent rule.
- (66) Further, a non-EU AIFM intending to manage EU AIFs and/or market AIFs in the Union with a passport should comply with a specific authorisation procedure and certain specific requirements concerning the third country of the non-EU AIFM and, as appropriate, the third country of the non-EU AIF should be satisfied.
- (67) ESMA should provide advice on the determination of the Member State of reference, and, where relevant, the exemption as regards compatibility with an equivalent rule. Specific requirements for the exchange of information between the competent authorities of the Member State of reference and the competent authorities of the host Member States of the AIFM should apply. Further, the mediation procedure provided for in Article 19 of Regulation (EU) No 1095/2010 should apply in case of disagreement between competent authorities of Member States on the determination of the Member State of reference, the application of the exemption in case of incompatibility between compliance with this Directive and compliance with equivalent rules of a third country, and the assessment regarding the fulfilment of the specific requirements concerning the third country of the non-EU AIFM and, as appropriate, the third country of the non-EU AIF.
- (68) ESMA should, on an annual basis, conduct a peer review analysis of the supervisory activities of the competent authorities in relation to the authorisation and the supervision of non-EU AIFMs, to further enhance consistency in supervisory outcomes, in accordance with Article 30 of Regulation (EU) No 1095/2010.
- (69) During a transitional period which will, in principle, taking into account ESMA's advice, be brought to an end by means of a delegated act 3 years after the establishment of the passport for non-EU AIFMs, a non-EU AIFM intending to market AIFs in certain Member States only and without such a passport should also be permitted to do so by the relevant Member States, but only in so far as certain minimum conditions are met. Those non-EU AIFMs should be subject at least to rules similar to those applicable to EU AIFMs managing EU AIFs with respect to the disclosure to investors. In order to facilitate the monitoring of systemic risk those non-EU AIFMs should also be subject to reporting obligations vis-à-vis the competent authorities of the Member State in which AIFs are marketed. Such AIFMs should therefore comply with the transparency requirements laid down in this Directive and the obligations on AIFMs managing AIFs which acquire control of non-listed companies and issuers. Further, appropriate cooperation arrangements for the purpose of systemic risk oversight and in line with international standards should be in place between the competent authorities of the Member States where the AIFs are marketed, if applicable, the competent authorities of the EU AIFs concerned and the supervisory authorities of the third country where the non-EU AIFM is established and, if applicable, the supervisory authorities of the third country where the non-EU AIF is established in order to ensure an efficient exchange of information that allows competent authorities of the relevant Member States to carry out their duties in accordance with this Directive. The cooperation arrangements should not be used as a barrier to impede third country funds from being marketed in a Member State. Finally, the third country where the non-EU AIFM or the non-EU AIF is established should not be listed as a Non-Cooperative Country and Territory by FATF.
- (70) This Directive should not affect the current situation, whereby a professional investor established in the Union may invest in AIFs on its own initiative, irrespective of where the AIFM and/or the AIF is established.
- (71) Member States should be able to allow the marketing of all or certain types of AIFs managed by AIFMs to retail investors in their territory. If a Member State allows the marketing of certain types of AIF, the Member State should make an assessment on a case-by-case basis to determine whether a specific AIF should be considered as a type of AIF which may be marketed to retail investors in its territory. Without prejudice to the application of other instruments of Union law, Member States should in such cases be able to impose stricter requirements on AIFs and AIFMs as a precondition for marketing to retail investors than is the case for AIFs marketed to professional investors in their territory, irrespective of whether such AIFs are marketed on a domestic or cross-border basis. Where a Member State allows the marketing of AIFs to retail investors in its territory, this possibility should be available regardless of the Member State where the AIFM managing the AIFs is established, and Member States should not impose stricter or additional requirements on EU AIFs established in another Member State and marketed on a cross-border basis than on AIFs marketed domestically. In addition, AIFMs, investment firms authorised under Directive 2004/39/EC and credit institutions authorised under

Directive 2006/48/EC which provide investment services to retail clients should take into account any additional requirements when assessing whether a certain AIF is suitable or appropriate for an individual retail client or whether it is a complex or non-complex financial instrument.

(72) It is necessary to clarify the powers and duties of the competent authorities responsible for implementing this Directive, and to strengthen the mechanisms necessary to ensure effective cross-border supervisory cooperation. Under certain circumstances it should be possible for the competent authorities of the host Member States of an AIFM to take direct action to supervise compliance with provisions for which they are responsible. For other provisions the competent authorities of the host Member States should under certain circumstances be allowed to request action from the competent authorities of the home Member State and to intervene if no such action is undertaken.

(73) This Directive provides for a general coordinating role for ESMA, and the possibility of binding mediation procedures, chaired by ESMA, to resolve disputes between competent authorities.

(74) ESMA should develop draft regulatory technical standards on the contents of the cooperation arrangements that must be concluded by the home Member State or by the Member State of reference of the AIFM and the relevant third-country supervisory authorities and on the procedures for the exchange of information. The draft regulatory technical standards should ensure that pursuant to those cooperation arrangements all necessary information is to be provided to enable the competent authorities of both the home and the host Member States to exercise their supervisory and investigatory powers under this Directive. ESMA should also have a facilitating role in the negotiation and conclusion of the cooperation arrangements. For example, ESMA should be able to use its facilitating role by providing for a standard format for such cooperation arrangements.

(75) Member States should lay down rules on penalties applicable to infringements of this Directive and ensure that they are implemented. The penalties should be effective, proportionate and dissuasive.

(76) This Directive respects the fundamental rights and observes the principles recognised, in particular, in the TFEU and in the Charter of Fundamental Rights of the European Union (Charter), in particular the right to the protection of personal data recognised in Article 16 TFEU and in Article 8 of the Charter. Any exchange or

transmission of information by competent authorities should be in accordance with the rules on the transfer of personal data as laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁽¹⁾. Any exchange or transmission of information by ESMA should be in accordance with the rules on the transfer of personal data as laid down in Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data⁽²⁾, which should be fully applicable to the processing of personal data for the purposes of this Directive.

(77) 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 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⁽³⁾.

(78) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU where expressly provided for in this Directive. In particular, the Commission should be empowered to adopt delegated acts to specify the methods of leverage as defined in this Directive, including any financial and/or legal structures involving third parties controlled by the relevant AIF where those structures are specifically set up to directly or indirectly create leverage at the level of the AIF. In particular for private equity and venture capital funds this means that leverage that exists at the level of a portfolio company is not intended to be included when referring to such financial or legal structures.

(79) Delegated acts should also be adopted to specify how to calculate the thresholds for the lighter regime and how to treat AIFMs whose assets under management, including any assets acquired through use of leverage, in one and the same calendar year occasionally exceed and/or fall below the relevant threshold; to specify the obligations to register for the AIFMs falling below the thresholds and to provide information in order to effectively monitor systemic risk and the obligation for such AIFMs to notify the relevant competent authorities where they no longer fulfil the conditions for application of the lighter regime.

⁽¹⁾ OJ L 281, 23.11.1995, p. 31.

⁽²⁾ OJ L 8, 12.1.2001, p. 1.

⁽³⁾ OJ L 55, 28.2.2011, p. 13.

- (80) Delegated acts should also be adopted to clarify the methods of leverage, including any financial and/or legal structures involving third parties controlled by the relevant AIF and how leverage is to be calculated; to specify the risks the additional own funds or the professional indemnity insurance must cover, the conditions for determining the appropriateness of additional own funds or the coverage of the professional indemnity insurance, and the manner of determining ongoing adjustments of the additional own funds or of the coverage of the professional indemnity insurance. Delegated acts should also be adopted to specify the criteria to be used by competent authorities to assess whether AIFMs comply with their obligations as regards their conduct of business, their obligation to act in the best interests of the AIFs or the investors of the AIFs they manage and the integrity of the market; to have and employ effectively the resources and procedures that are necessary for the proper performance of their business activities; to take all reasonable steps to avoid conflicts of interest and, where such conflicts cannot be avoided, to identify, manage and monitor, and where applicable, disclose, those conflicts of interest in order to prevent them from adversely affecting the interests of the AIFs and their investors and to ensure that the AIFs they manage are fairly treated; to comply with all regulatory requirements applicable to the conduct of their business activities so as to promote the best interests of the AIFs or the investors of the AIFs they manage and the integrity of the market; and to treat all AIF investors fairly.
- (81) Delegated acts should also be adopted to specify the type of conflicts of interest AIFMs have to identify, as well as the reasonable steps AIFMs are expected to take in terms of structures and organisational and administrative procedures in order to identify, prevent, manage, monitor and disclose conflicts of interest. Delegated acts should also be adopted to specify the risk management functions to be employed; the appropriate frequency for review of the risk management system; how the risk management function should be functionally and hierarchically separated from the operating units, including the portfolio management function; the specific safeguards against conflicts of interest; and the risk management requirements to be employed by AIFMs. Delegated acts should also be adopted to specify the liquidity management systems and procedures that AIFMs should employ and the alignment of the investment strategy, liquidity profile and redemption policy. Delegated acts should also be adopted to specify the requirements that the originators, the sponsors or the original lenders of securitisation instruments have to meet in order for an AIFM to be allowed to invest in such instruments issued after 1 January 2011.
- (82) Delegated acts should also be adopted to specify the requirements that AIFMs have to comply with when investing in such securitisation instruments; to specify administrative and accounting procedures, control and safeguard arrangements for electronic data processing and adequate internal control mechanisms; to specify the procedures for the proper valuation of the assets and the calculation of the net asset value per unit or share of the AIF, the professional guarantees the external valuer must be able to provide, and the frequency for valuation appropriate for open-ended AIFs.
- (83) Delegated acts should also be adopted to specify the conditions subject to which the delegation of AIFM functions should be approved and the conditions subject to which the AIFM has delegated its functions to the extent that it becomes a letter-box entity and can no longer be considered to be the manager of the AIF; as regards depositaries, to specify the criteria for assessing that the prudential regulation and supervision of third countries where the depositaries are established have the same effect as Union law and are effectively enforced, the particulars that need to be included in the standard agreement, the conditions for performing the depositary functions, including the type of financial instruments that should be included in the scope of the depositary's custody duties, the conditions subject to which the depositary may exercise its custody duties over financial instruments registered with a central depositary and the conditions subject to which the depositary should safekeep the financial instruments issued in a nominative form and registered with an issuer or a registrar, the due diligence duties of depositaries, the segregation obligation, the conditions subject to and circumstances in which financial instruments held in custody should be considered as lost, what is to be understood by external events beyond reasonable control, the consequences of which would have been unavoidable despite all reasonable efforts to the contrary, and the conditions subject to and circumstances in which there is an objective reason to contract a discharge of liability. Delegated acts should also be adopted to specify the content and format of the annual report that AIFMs have to make available for each AIF they manage and to specify the disclosure obligations of AIFMs to investors and reporting requirements to competent authorities as well as their frequency.
- (84) Delegated acts should also be adopted to specify when leverage is considered to be employed on a substantial basis and the principles competent authorities should use when considering imposing limits to the level of leverage that an AIFM can apply. Delegated acts should also be adopted to specify the cooperation arrangements in relation to non-EU AIFMs and/or non-EU AIFs in order to design a common framework to facilitate the establishment of those cooperation arrangements with third

- countries. Delegated acts should also be adopted to specify the content of exchange of information regarding AIFMs between competent authorities and the provision of certain information to ESMA.
- (85) Depending on the advice of ESMA in this regard and the criteria set out in this Directive, a delegated act should also be adopted in order to extend the passport to EU AIFMs marketing non-EU AIFs in the Union and to non-EU AIFMs managing and/or marketing AIFs in the Union, and another delegated act should be adopted to terminate the application of national private placement regimes in this regard.
- (86) The European Parliament and the Council should have 3 months from the date of notification to object to a delegated act. At the initiative of the European Parliament or the Council, it should be possible to prolong that period by 3 months in 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 important where deadlines need to be met, for example to allow Member States to transpose delegated acts within the transposition period laid down in this Directive, where relevant.
- (87) In the Declaration 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 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.
- (88) 2 years after the deadline for transposition of this Directive, ESMA should issue an opinion on the functioning of the passport then in force and on the functioning of national private placement regimes. It should also issue advice on the extension of the passport to EU AIFMs marketing non-EU AIFs in the Union and to non-EU AIFMs managing and/or marketing AIFs in the Union. The Commission should adopt a delegated act within 3 months after having received that opinion and advice from ESMA and taking into account the criteria listed in, and the objectives of, this Directive, inter alia, regarding the internal market, investor protection and the effective monitoring of systemic risk, specifying the date when the rules relating to the extension of the passport provided for in this Directive should become applicable in all Member States.
- (89) At the April 2009 summit in London, G20 Leaders agreed that hedge funds or their managers should be registered and should be required to disclose appropriate information on an ongoing basis to supervisors or regulators. They should be subject to oversight to ensure that they have adequate risk management. In June 2010, G20 Leaders in Toronto reaffirmed their commitment and also committed to accelerate the implementation of strong measures to improve transparency and regulatory oversight of hedge funds in an internationally consistent and non-discriminatory way. In order to support the G20 objectives, the International Organization of Securities Commissions issued high level principles of hedge fund oversight in June 2009 to guide the development of internationally consistent regulation in this area. On 16 September 2010 the European Council agreed on the need for Europe to promote its interest and values more assertively and in a spirit of reciprocity and mutual benefit in the context of the Union's external relations and to take steps to, inter alia, secure greater market access for European business and deepen regulatory cooperation with major trade partners. The Commission will endeavour to ensure that these commitments are implemented in a similar way by the Union's international partners.
- (90) 3 years after the entry into force of the delegated act pursuant to which the passport is to apply to all AIFMs, ESMA should issue an opinion on the functioning of the passport then in force and on the functioning of national private placement regimes. It should also issue advice on the termination of those national regimes. The Commission should adopt a delegated act within 3 months of receipt of the opinion and advice from ESMA, taking into account the criteria listed in, and the objectives of, this Directive, inter alia, relating to the internal market, investor protection and the effective monitoring of systemic risk, specifying the date when the national regimes referred to in this Directive should be brought to an end in all Member States.
- (91) 4 years after the deadline for transposition of this Directive, the Commission should, on the basis of public consultation and in the light of the discussions with competent authorities, commence a review of the application and the scope of this Directive. That review should analyse the experience acquired in applying this Directive, its impact on investors, AIFs or AIFMs, in the Union and in third countries, and the extent to which the objectives of this Directive have been achieved, if necessary proposing appropriate amendments. That review should include a general survey of the functioning of the rules laid down in this Directive and the experience acquired in applying them. The Commission should in its review examine the functions of ESMA and the Union competent authorities in ensuring effective supervision of all AIFMs operating in the Union markets

in the context of this Directive, including, inter alia – in accordance with Regulation (EU) No 1095/2010 – entrusting ESMA with further supervisory responsibilities in the field of authorisation and supervision of non-EU AIFMs. In this context the Commission should assess the costs and benefits of entrusting ESMA with such tasks.

- (92) This Directive aims at establishing a framework capable of addressing the potential risks which might arise from the activities of AIFMs and ensuring the effective monitoring of those risks by the competent authorities within the Union. It is necessary to provide for a stringent regulatory and supervisory framework which leaves no gaps in financial regulation. In that regard reference is made to the existing due diligence requirements applicable to professional investors pursuant to the relevant regulation applicable to such investors. The Commission is invited to review the relevant legislation with respect to professional investors in order to assess the need for tighter requirements regarding the due diligence process to be undertaken by Union professional investors investing on their own initiative in non-EU financial products, such as non-EU AIFs.
- (93) At the end of its review, the Commission should present a report to the European Parliament and the Council including, if appropriate, proposed amendments taking into account the objectives of this Directive and potential impacts on investors, AIFs or AIFMs, in the Union and in third countries.
- (94) Since the objective of this Directive, namely to ensure a high level of investor protection by laying down a common framework for the authorisation and supervision of AIFMs, cannot be sufficiently achieved by the Member States, as evidenced by the deficiencies of existing nationally based regulation and oversight of those actors, and can therefore 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.
- (95) Directives 2003/41/EC and 2009/65/EC, Regulation (EC) No 1060/2009 of the European Parliament and of the Council of 16 September 2009 on credit rating agencies ⁽¹⁾ and Regulation (EU) No 1095/2010 should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

This Directive lays down the rules for the authorisation, ongoing operation and transparency of the managers of alternative investment funds (AIFMs) which manage and/or market alternative investment funds (AIFs) in the Union.

Article 2

Scope

1. Subject to paragraph 3 of this Article and to Article 3, this Directive shall apply to:
 - (a) EU AIFMs which manage one or more AIFs irrespective of whether such AIFs are EU AIFs or non-EU AIFs;
 - (b) non-EU AIFMs which manage one or more EU AIFs; and
 - (c) non-EU AIFMs which market one or more AIFs in the Union irrespective of whether such AIFs are EU AIFs or non-EU AIFs.
2. For the purposes of paragraph 1, the following shall be of no significance:
 - (a) whether the AIF belongs to the open-ended or closed-ended type;
 - (b) whether the AIF is constituted under the law of contract, under trust law, under statute, or has any other legal form;
 - (c) the legal structure of the AIFM.
3. This Directive shall not apply to the following entities:
 - (a) holding companies;
 - (b) institutions for occupational retirement provision which are covered by Directive 2003/41/EC, including, where applicable, the authorised entities responsible for managing such institutions and acting on their behalf referred to in Article 2(1) of that Directive or the investment managers appointed pursuant to Article 19(1) of that Directive, in so far as they do not manage AIFs;
 - (c) supranational institutions, such as the European Central Bank, the European Investment Bank, the European Investment Fund, the European Development Finance Institutions and bilateral development banks, the World Bank, the International Monetary Fund, and other supranational institutions and similar international organisations, in the event that such institutions or organisations manage AIFs and in so far as those AIFs act in the public interest;
 - (d) national central banks;

⁽¹⁾ OJ L 302, 17.11.2009, p. 1.

- (e) national, regional and local governments and bodies or other institutions which manage funds supporting social security and pension systems;
- (f) employee participation schemes or employee savings schemes;
- (g) securitisation special purpose entities.

4. Member States shall take the necessary steps to ensure that AIFMs referred to in paragraph 1 comply with this Directive at all times.

Article 3

Exemptions

1. This Directive shall not apply to AIFMs in so far as they manage one or more AIFs whose only investors are the AIFM or the parent undertakings or the subsidiaries of the AIFM or other subsidiaries of those parent undertakings, provided that none of those investors is itself an AIF.

2. Without prejudice to the application of Article 46, only paragraphs 3 and 4 of this Article shall apply to the following AIFMs:

- (a) AIFMs which either directly or indirectly, through a company with which the AIFM is linked by common management or control, or by a substantive direct or indirect holding, manage portfolios of AIFs whose assets under management, including any assets acquired through use of leverage, in total do not exceed a threshold of EUR 100 million; or
- (b) AIFMs which either directly or indirectly, through a company with which the AIFM is linked by common management or control, or by a substantive direct or indirect holding, manage portfolios of AIFs whose assets under management in total do not exceed a threshold of EUR 500 million when the portfolios of AIFs consist of AIFs that are unleveraged and have no redemption rights exercisable during a period of 5 years following the date of initial investment in each AIF.

3. Member States shall ensure that AIFMs referred to in paragraph 2 at least:

- (a) are subject to registration with the competent authorities of their home Member State;
- (b) identify themselves and the AIFs that they manage to the competent authorities of their home Member State at the time of registration;

(c) provide information on the investment strategies of the AIFs that they manage to the competent authorities of their home Member State at the time of registration;

(d) regularly provide the competent authorities of their home Member State with information on the main instruments in which they are trading and on the principal exposures and most important concentrations of the AIFs that they manage in order to enable the competent authorities to monitor systemic risk effectively; and

(e) notify the competent authorities of their home Member State in the event that they no longer meet the conditions referred to in paragraph 2.

This paragraph and paragraph 2 shall apply without prejudice to any stricter rules adopted by Member States with respect to AIFMs referred to in paragraph 2.

Member States shall take the necessary steps to ensure that where the conditions set out in paragraph 2 are no longer met, the AIFM concerned applies for authorisation within 30 calendar days in accordance with the relevant procedures laid down in this Directive.

4. AIFMs referred to in paragraph 2 shall not benefit from any of the rights granted under this Directive unless they choose to opt in under this Directive. Where AIFMs opt in, this Directive shall become applicable in its entirety.

5. The Commission shall adopt implementing acts with a view to specifying the procedures for AIFMs which choose to opt in under this Directive in accordance with paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 59(2).

6. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) how the thresholds referred to in paragraph 2 are to be calculated and the treatment of AIFMs which manage AIFs whose assets under management, including any assets acquired through the use of leverage, occasionally exceed and/or fall below the relevant threshold in the same calendar year;
- (b) the obligation to register and to provide information in order to allow effective monitoring of systemic risk as set out in paragraph 3; and
- (c) the obligation to notify competent authorities as set out in paragraph 3.

Article 4

Definitions

1. For the purpose of this Directive, the following definitions shall apply:

(a) 'AIFs' means collective investment undertakings, including investment compartments thereof, which:

(i) raise capital from a number of investors, with a view to investing it in accordance with a defined investment policy for the benefit of those investors; and

(ii) do not require authorisation pursuant to Article 5 of Directive 2009/65/EC;

(b) 'AIFMs' means legal persons whose regular business is managing one or more AIFs;

(c) 'branch' when relating to an AIFM means a place of business which is a part of an AIFM, which has no legal personality and which provides the services for which the AIFM has been authorised; all the places of business established in the same Member State by an AIFM with its registered office in another Member State or in a third country shall be regarded as a single branch;

(d) 'carried interest' means a share in the profits of the AIF accrued to the AIFM as compensation for the management of the AIF and excluding any share in the profits of the AIF accrued to the AIFM as a return on any investment by the AIFM into the AIF;

(e) 'close links' means a situation in which two or more natural or legal persons are linked by:

(i) participation, namely ownership, directly or by way of control, of 20 % or more of the voting rights or capital of an undertaking;

(ii) control, namely the relationship between a parent undertaking and a subsidiary, as referred to in Article 1 of the Seventh Council Directive 83/349/EEC of 13 June 1983 on consolidated accounts⁽¹⁾, or a similar relationship between a natural or legal person and an undertaking; for the purposes of this point a subsidiary undertaking of a subsidiary undertaking shall also be considered to be a subsidiary of the parent undertaking of those subsidiaries.

A situation in which two or more natural or legal persons are permanently linked to the same person by a control relationship shall also be regarded as constituting a 'close link' between such persons;

(f) 'competent authorities' means the national authorities of Member States which are empowered by law or regulation to supervise AIFMs;

(g) 'competent authorities' in relation to a depositary means:

(i) if the depositary is a credit institution authorised under Directive 2006/48/EC, the competent authorities as defined in point (4) of Article 4 thereof;

(ii) if the depositary is an investment firm authorised under Directive 2004/39/EC, the competent authorities as defined in point (22) of Article 4(1) thereof;

(iii) if the depositary falls within a category of institution referred to in point (c) of the first subparagraph of Article 21(3) of this Directive, the national authorities of its home Member State which are empowered by law or regulation to supervise such categories of institution;

(iv) if the depositary is an entity referred to in the third subparagraph of Article 21(3) of this Directive, the national authorities of the Member State in which that entity has its registered office and which are empowered by law or regulation to supervise such entity or the official body competent to register or supervise such entity pursuant to the rules of professional conduct applicable thereto;

(v) if the depositary is appointed as depositary for a non-EU AIF in accordance with point (b) of Article 21(5) of this Directive and does not fall within the scope of points (i) to (iv) of this point, the relevant national authorities of the third country where the depositary has its registered office;

(h) 'competent authorities of the EU AIF' means the national authorities of a Member State which are empowered by law or regulation to supervise AIFs;

(i) 'control' means control as defined in Article 1 of Directive 83/349/EEC;

⁽¹⁾ OJ L 193, 18.7.1983, p. 1.

- (j) 'established' means:
- (i) for AIFMs, 'having its registered office in';
 - (ii) for AIFs, 'being authorised or registered in', or, if the AIF is not authorised or registered, 'having its registered office in';
 - (iii) for depositaries, 'having its registered office or branch in';
 - (iv) for legal representatives that are legal persons, 'having its registered office or branch in';
 - (v) for legal representatives that are natural persons, 'domiciled in';
- (k) 'EU AIF' means:
- (i) an AIF which is authorised or registered in a Member State under the applicable national law; or
 - (ii) an AIF which is not authorised or registered in a Member State, but has its registered office and/or head office in a Member State;
- (l) 'EU AIFM' means an AIFM which has its registered office in a Member State;
- (m) 'feeder AIF' means an AIF which:
- (i) invests at least 85 % of its assets in units or shares of another AIF (the 'master AIF');
 - (ii) invests at least 85 % of its assets in more than one master AIFs where those master AIFs have identical investment strategies; or
 - (iii) has otherwise an exposure of at least 85 % of its assets to such a master AIF;
- (n) 'financial instrument' means an instrument as specified in Section C of Annex I to Directive 2004/39/EC;
- (o) 'holding company' means a company with shareholdings in one or more other companies, the commercial purpose of which is to carry out a business strategy or strategies through its subsidiaries, associated companies or participations in order to contribute to their long-term value, and which is either a company:
- (i) operating on its own account and whose shares are admitted to trading on a regulated market in the Union; or
 - (ii) not established for the main purpose of generating returns for its investors by means of divestment of its subsidiaries or associated companies, as evidenced in its annual report or other official documents;
- (p) 'home Member State of the AIF' means:
- (i) the Member State in which the AIF is authorised or registered under applicable national law, or in case of multiple authorisations or registrations, the Member State in which the AIF has been authorised or registered for the first time; or
 - (ii) if the AIF is neither authorised nor registered in a Member State, the Member State in which the AIF has its registered office and/or head office;
- (q) 'home Member State of the AIFM' means the Member State in which the AIFM has its registered office; for non-EU AIFMs, all references to 'home Member State of the AIFM' in this Directive shall be read as the 'Member State of reference', as provided for in Chapter VII;
- (r) 'host Member State of the AIFM' means any of the following:
- (i) a Member State, other than the home Member State, in which an EU AIFM manages EU AIFs;
 - (ii) a Member State, other than the home Member State, in which an EU AIFM markets units or shares of an EU AIF;
 - (iii) a Member State, other than the home Member State, in which an EU AIFM markets units or shares of a non-EU AIF;
 - (iv) a Member State, other than the Member State of reference, in which a non-EU AIFM manages EU AIFs;
 - (v) a Member State, other than the Member State of reference, in which a non-EU AIFM markets units or shares of an EU AIF; or
 - (vi) a Member State, other than the Member State of reference, in which a non-EU AIFM markets units or shares of a non-EU AIF;

- (s) 'initial capital' means funds as referred to in points (a) and (b) of the first paragraph of Article 57 of Directive 2006/48/EC;
- (t) 'issuer' means an issuer within the meaning of point (d) of Article 2(1) of Directive 2004/109/EC where that issuer has its registered office in the Union, and where its shares are admitted to trading on a regulated market within the meaning of point (14) of Article 4(1) of Directive 2004/39/EC;
- (u) 'legal representative' means a natural person domiciled in the Union or a legal person with its registered office in the Union, and which, expressly designated by a non-EU AIFM, acts on behalf of such non-EU AIFM vis-à-vis the authorities, clients, bodies and counterparties to the non-EU AIFM in the Union with regard to the non-EU AIFM's obligations under this Directive;
- (v) 'leverage' means any method by which the AIFM increases the exposure of an AIF it manages whether through borrowing of cash or securities, or leverage embedded in derivative positions or by any other means;
- (w) 'managing AIFs' means performing at least investment management functions referred to in point 1(a) or (b) of Annex I for one or more AIFs;
- (x) 'marketing' means a direct or indirect offering or placement at the initiative of the AIFM or on behalf of the AIFM of units or shares of an AIF it manages to or with investors domiciled or with a registered office in the Union;
- (y) 'master AIF' means an AIF in which another AIF invests or has an exposure in accordance with point (m);
- (z) 'Member State of reference' means the Member State determined in accordance with Article 37(4);
- (aa) 'non-EU AIF' means an AIF which is not an EU AIF;
- (ab) 'non-EU AIFM' means an AIFM which is not an EU AIFM;
- (ac) 'non-listed company' means a company which has its registered office in the Union and the shares of which are not admitted to trading on a regulated market within the meaning of point (14) of Article 4(1) of Directive 2004/39/EC;
- (ad) 'own funds' means own funds as referred to in Articles 56 to 67 of Directive 2006/48/EC;
- (ae) 'parent undertaking' means a parent undertaking within the meaning of Articles 1 and 2 of Directive 83/349/EEC;
- (af) 'prime broker' means a credit institution, a regulated investment firm or another entity subject to prudential regulation and ongoing supervision, offering services to professional investors primarily to finance or execute transactions in financial instruments as counterparty and which may also provide other services such as clearing and settlement of trades, custodial services, securities lending, customised technology and operational support facilities;
- (ag) 'professional investor' means an investor which is considered to be a professional client or may, on request, be treated as a professional client within the meaning of Annex II to Directive 2004/39/EC;
- (ah) 'qualifying holding' means a direct or indirect holding in an AIFM which represents 10 % or more of the capital or of the voting rights, in accordance with Articles 9 and 10 of Directive 2004/109/EC, taking into account the conditions regarding aggregation of the holding laid down in Article 12(4) and (5) thereof, or which makes it possible to exercise a significant influence over the management of the AIFM in which that holding subsists;
- (ai) 'employees' representatives' means employees' representatives as defined in point (e) of Article 2 of Directive 2002/14/EC;
- (aj) 'retail investor' means an investor who is not a professional investor;
- (ak) 'subsidiary' means a subsidiary undertaking as defined in Articles 1 and 2 of Directive 83/349/EEC;
- (al) 'supervisory authorities' in relation to non-EU AIFs means the national authorities of a third country which are empowered by law or regulation to supervise AIFs;
- (am) 'supervisory authorities' in relation to non-EU AIFMs means the national authorities of a third country which are empowered by law or regulation to supervise AIFMs;

(an) 'securitisation special purpose entities' means entities whose sole purpose is to carry on a securitisation or securitisations within the meaning of Article 1(2) of Regulation (EC) No 24/2009 of the European Central Bank of 19 December 2008 concerning statistics on the assets and liabilities of financial vehicle corporations engaged in securitisation transactions⁽¹⁾ and other activities which are appropriate to accomplish that purpose;

(ao) 'UCITS' means an undertaking for collective investment in transferable securities authorised in accordance with Article 5 of Directive 2009/65/EC.

2. For the purposes of point (ad) of paragraph 1 of this Article, Articles 13 to 16 of Directive 2006/49/EC of the European Parliament and of the Council of 14 June 2006 on the capital adequacy of investment firms and credit institutions⁽²⁾ shall apply *mutatis mutandis*.

3. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

(a) the methods of leverage, as defined in point (v) of paragraph 1, including any financial and/or legal structures involving third parties controlled by the relevant AIF; and

(b) how leverage is to be calculated.

4. The European Supervisory Authority (European Securities and Markets Authority) (ESMA) shall develop draft regulatory technical standards to determine types of AIFMs, where relevant in the application of this Directive, and to ensure uniform conditions of application of this Directive.

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.

Article 5

Determination of the AIFM

1. Member States shall ensure that each AIF managed within the scope of this Directive shall have a single AIFM, which shall be responsible for ensuring compliance with this Directive. The AIFM shall be either:

(a) an external manager, which is the legal person appointed by the AIF or on behalf of the AIF and which through this appointment is responsible for managing the AIF (external AIFM); or

(b) where the legal form of the AIF permits an internal management and where the AIF's governing body chooses not to appoint an external AIFM, the AIF itself, which shall then be authorised as AIFM.

2. In cases where an external AIFM is unable to ensure compliance with requirements of this Directive for which an AIF or another entity on its behalf is responsible, it shall immediately inform the competent authorities of its home Member State and, if applicable, the competent authorities of the EU AIF concerned. The competent authorities of the home Member State of the AIFM shall require the AIFM to take the necessary steps to remedy the situation.

3. If, notwithstanding the steps referred to in paragraph 2 being taken, the non-compliance persists, and in so far as it concerns an EU AIFM or an EU AIF, the competent authorities of the home Member State of the AIFM shall require that it resign as AIFM of that AIF. In that case the AIF shall no longer be marketed in the Union. If it concerns a non-EU AIFM managing a non-EU AIF, the AIF shall no longer be marketed in the Union. The competent authorities of the home Member State of the AIFM shall immediately inform the competent authorities of the host Member States of the AIFM.

CHAPTER II

AUTHORISATION OF AIFMs

Article 6

Conditions for taking up activities as AIFM

1. Member States shall ensure that no AIFMs manage AIFs unless they are authorised in accordance with this Directive.

AIFMs authorised in accordance with this Directive shall meet the conditions for authorisation established in this Directive at all times.

2. Member States shall require that no external AIFM engage in activities other than those referred to in Annex I to this Directive and the additional management of UCITS subject to authorisation under Directive 2009/65/EC.

3. Member States shall require that no internally managed AIF shall engage in activities other than the internal management of that AIF in accordance with Annex I.

4. By way of derogation from paragraph 2, Member States may authorise an external AIFM to provide the following services:

(a) management of portfolios of investments, including those owned by pension funds and institutions for occupational retirement provision in accordance with Article 19(1) of Directive 2003/41/EC, in accordance with mandates given by investors on a discretionary, client-by-client basis;

⁽¹⁾ OJ L 15, 20.1.2009, p. 1.

⁽²⁾ OJ L 177, 30.6.2006, p. 201.

- (b) non-core services comprising:
- (i) investment advice;
 - (ii) safe-keeping and administration in relation to shares or units of collective investment undertakings;
 - (iii) reception and transmission of orders in relation to financial instruments.
5. AIFMs shall not be authorised under this Directive to provide:
- (a) only the services referred to in paragraph 4;
 - (b) non-core services referred to in point (b) of paragraph 4 without also being authorised to provide the services referred to in point (a) of paragraph 4;
 - (c) only the activities referred to in point 2 of Annex I; or
 - (d) the services referred to in point 1(a) of Annex I without also providing the services referred to in point 1(b) of Annex I or vice versa.
6. Article 2(2) and Articles 12, 13 and 19 of Directive 2004/39/EC shall apply to the provision of the services referred to in paragraph 4 of this Article by AIFMs.
7. Member States shall require that the AIFMs provide the competent authorities of their home Member State with the information they require to monitor compliance with the conditions referred to in this Directive at all times.
8. Investment firms authorised under Directive 2004/39/EC and credit institutions authorised under Directive 2006/48/EC shall not be required to obtain an authorisation under this Directive in order to provide investment services such as individual portfolio management in respect of AIFs. However, investment firms shall, directly or indirectly, offer units or shares of AIFs to, or place such units or shares with, investors in the Union, only to the extent the units or shares can be marketed in accordance with this Directive.
- Article 7*
- Application for authorisation**
1. Member States shall require that AIFMs apply for authorisation from the competent authorities of their home Member State.
2. Member States shall require that an AIFM applying for an authorisation shall provide the following information relating to the AIFM to the competent authorities of its home Member State:
- (a) information on the persons effectively conducting the business of the AIFM;
 - (b) information on the identities of the AIFM's shareholders or members, whether direct or indirect, natural or legal persons, that have qualifying holdings and on the amounts of those holdings;
 - (c) a programme of activity setting out the organisational structure of the AIFM, including information on how the AIFM intends to comply with its obligations under Chapters II, III, IV, and, where applicable, Chapters V, VI, VII and VIII;
 - (d) information on the remuneration policies and practices pursuant to Article 13;
 - (e) information on arrangements made for the delegation and sub-delegation to third parties of functions as referred to in Article 20.
3. Member States shall require that an AIFM applying for authorisation further provide the following information on the AIFs it intends to manage to the competent authorities of its home Member State:
- (a) information about the investment strategies including the types of underlying funds if the AIF is a fund of funds, and the AIFM's policy as regards the use of leverage, and the risk profiles and other characteristics of the AIFs it manages or intends to manage, including information about the Member States or third countries in which such AIFs are established or are expected to be established;
 - (b) information on where the master AIF is established if the AIF is a feeder AIF;
 - (c) the rules or instruments of incorporation of each AIF the AIFM intends to manage;
 - (d) information on the arrangements made for the appointment of the depositary in accordance with Article 21 for each AIF the AIFM intends to manage;
 - (e) any additional information referred to in Article 23(1) for each AIF the AIFM manages or intends to manage.
4. Where a management company is authorised pursuant to Directive 2009/65/EC (UCITS management company) and applies for authorisation as an AIFM under this Directive, the competent authorities shall not require the UCITS management company to provide information or documents which the UCITS management company has already provided when applying for authorisation under Directive 2009/65/EC, provided that such information or documents remain up-to-date.

1. Member States shall require that AIFMs apply for authorisation from the competent authorities of their home Member State.

2. Member States shall require that an AIFM applying for an authorisation shall provide the following information relating to the AIFM to the competent authorities of its home Member State:

- (a) information on the persons effectively conducting the business of the AIFM;
 - (b) information on the identities of the AIFM's shareholders or members, whether direct or indirect, natural or legal persons, that have qualifying holdings and on the amounts of those holdings;
 - (c) a programme of activity setting out the organisational structure of the AIFM, including information on how the AIFM intends to comply with its obligations under Chapters II, III, IV, and, where applicable, Chapters V, VI, VII and VIII;
 - (d) information on the remuneration policies and practices pursuant to Article 13;
 - (e) information on arrangements made for the delegation and sub-delegation to third parties of functions as referred to in Article 20.
3. Member States shall require that an AIFM applying for authorisation further provide the following information on the AIFs it intends to manage to the competent authorities of its home Member State:
- (a) information about the investment strategies including the types of underlying funds if the AIF is a fund of funds, and the AIFM's policy as regards the use of leverage, and the risk profiles and other characteristics of the AIFs it manages or intends to manage, including information about the Member States or third countries in which such AIFs are established or are expected to be established;
 - (b) information on where the master AIF is established if the AIF is a feeder AIF;
 - (c) the rules or instruments of incorporation of each AIF the AIFM intends to manage;
 - (d) information on the arrangements made for the appointment of the depositary in accordance with Article 21 for each AIF the AIFM intends to manage;
 - (e) any additional information referred to in Article 23(1) for each AIF the AIFM manages or intends to manage.
4. Where a management company is authorised pursuant to Directive 2009/65/EC (UCITS management company) and applies for authorisation as an AIFM under this Directive, the competent authorities shall not require the UCITS management company to provide information or documents which the UCITS management company has already provided when applying for authorisation under Directive 2009/65/EC, provided that such information or documents remain up-to-date.

5. The competent authorities shall, on a quarterly basis, inform ESMA of authorisations granted or withdrawn in accordance with this Chapter.

ESMA shall keep a central public register identifying each AIFM authorised under this Directive, a list of the AIFs managed and/or marketed in the Union by such AIFMs and the competent authority for each such AIFM. The register shall be made available in electronic format.

6. In order to ensure consistent harmonisation of this Article, ESMA may develop draft regulatory technical standards to specify the information to be provided to the competent authorities in the application for the authorisation of the AIFM, including the programme of activity.

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.

7. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to determine standard forms, templates and procedures for the provision of information provided for in the first subparagraph of paragraph 6.

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 1095/2010.

Article 8

Conditions for granting authorisation

1. The competent authorities of the home Member State of the AIFM shall not grant authorisation unless:

- (a) they are satisfied that the AIFM will be able to meet the conditions of this Directive;
- (b) the AIFM has sufficient initial capital and own funds in accordance with Article 9;
- (c) the persons who effectively conduct the business of the AIFM are of sufficiently good repute and are sufficiently experienced also in relation to the investment strategies pursued by the AIFs managed by the AIFM, the names of those persons and of every person succeeding them in office being communicated forthwith to the competent authorities of the home Member State of the AIFM and the conduct of the business of the AIFM being decided by at least two persons meeting such conditions;
- (d) the shareholders or members of the AIFM that have qualifying holdings are suitable taking into account the need to ensure the sound and prudent management of the AIFM; and

(e) the head office and the registered office of the AIFM are located in the same Member State.

Authorisation shall be valid for all Member States.

2. The relevant competent authorities of the other Member States involved shall be consulted before authorisation is granted to the following AIFMs:

- (a) a subsidiary of another AIFM, of a UCITS management company, of an investment firm, of a credit institution or of an insurance undertaking authorised in another Member State;
- (b) a subsidiary of the parent undertaking of another AIFM, of a UCITS management company, of an investment firm, of a credit institution or of an insurance undertaking authorised in another Member State; and
- (c) a company controlled by the same natural or legal persons as those that control another AIFM, a UCITS management company, an investment firm, a credit institution or an insurance undertaking authorised in another Member State.

3. The competent authorities of the home Member State of the AIFM shall refuse authorisation where the effective exercise of their supervisory functions is prevented by any of the following:

- (a) close links between the AIFM and other natural or legal persons;
- (b) the laws, regulations or administrative provisions of a third country governing natural or legal persons with which the AIFM has close links;
- (c) difficulties involved in the enforcement of those laws, regulations and administrative provisions.

4. The competent authorities of the home Member State of the AIFM may restrict the scope of the authorisation, in particular as regards the investment strategies of AIFs the AIFM is allowed to manage.

5. The competent authorities of the home Member State of the AIFM shall inform the applicant in writing within 3 months of the submission of a complete application, whether or not authorisation has been granted. The competent authorities may prolong this period for up to three additional months, where they consider it necessary due to the specific circumstances of the case and after having notified the AIFM accordingly.

For the purpose of this paragraph an application is deemed complete if the AIFM has at least submitted the information referred to in points (a) to (d) of Article 7(2) and points (a) and (b) of Article 7(3).

AIFMs may start managing AIFs with investment strategies described in the application in accordance with point (a) of Article 7(3) in their home Member State as soon as the authorisation is granted, but not earlier than 1 month after having submitted any missing information referred to in point (e) of Article 7(2) and points (c), (d) and (e) of Article 7(3).

6. In order to ensure consistent harmonisation of this Article, ESMA may develop draft regulatory technical standards to specify the:

- (a) requirements applicable to the AIFMs under paragraph 3;
- (b) requirements applicable to shareholders and members with qualifying holdings referred to in point (d) of paragraph 1;
- (c) obstacles which may prevent effective exercise of the supervisory functions of the competent authorities.

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.

Article 9

Initial capital and own funds

1. Member States shall require that an AIFM which is an internally managed AIF has an initial capital of at least EUR 300 000.

2. Where an AIFM is appointed as external manager of AIFs, the AIFM shall have an initial capital of at least EUR 125 000.

3. Where the value of the portfolios of AIFs managed by the AIFM exceeds EUR 250 million, the AIFM shall provide an additional amount of own funds. That additional amount of own funds shall be equal to 0,02 % of the amount by which the value of the portfolios of the AIFM exceeds EUR 250 million but the required total of the initial capital and the additional amount shall not, however, exceed EUR 10 million.

4. For the purpose of paragraph 3, AIFs managed by the AIFM, including AIFs for which the AIFM has delegated functions in accordance with Article 20 but excluding AIF portfolios that the AIFM is managing under delegation, shall be deemed to be the portfolios of the AIFM.

5. Irrespective of paragraph 3, the own funds of the AIFM shall never be less than the amount required under Article 21 of Directive 2006/49/EC.

6. Member States may authorise AIFMs not to provide up to 50 % of the additional amount of own funds referred to in

paragraph 3 if they benefit from a guarantee of the same amount given by a credit institution or an insurance undertaking which has its registered office in a Member State, or in a third country where it is subject to prudential rules considered by the competent authorities as equivalent to those laid down in Union law.

7. To cover potential professional liability risks resulting from activities AIFMs may carry out pursuant to this Directive, both internally managed AIFs and external AIFMs shall either:

- (a) have additional own funds which are appropriate to cover potential liability risks arising from professional negligence; or
- (b) hold a professional indemnity insurance against liability arising from professional negligence which is appropriate to the risks covered.

8. Own funds, including any additional own funds as referred to in point (a) of paragraph 7, shall be invested in liquid assets or assets readily convertible to cash in the short term and shall not include speculative positions.

9. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures in relation to paragraph 7 of this Article specifying:

- (a) the risks the additional own funds or the professional indemnity insurance must cover;
- (b) the conditions for determining the appropriateness of additional own funds or the coverage of the professional indemnity insurance; and
- (c) the manner of determining ongoing adjustments of the additional own funds or of the coverage of the professional indemnity insurance.

10. With the exception of paragraphs 7 and 8 and of the delegated acts adopted pursuant to paragraph 9, this Article shall not apply to AIFMs which are also UCITS management companies.

Article 10

Changes in the scope of the authorisation

1. Member States shall require that AIFMs, before implementation, notify the competent authorities of their home Member State of any material changes to the conditions for initial authorisation, in particular material changes to the information provided in accordance with Article 7.

2. If the competent authorities of the home Member State decide to impose restrictions or reject those changes, they shall, within 1 month of receipt of that notification, inform the AIFM. The competent authorities may prolong that period for up to 1 month where they consider this to be necessary because of the specific circumstances of the case and after having notified the AIFM accordingly. The changes shall be implemented if the relevant competent authorities do not oppose the changes within the relevant assessment period.

Article 11

Withdrawal of the authorisation

The competent authorities of the home Member State of the AIFM may withdraw the authorisation issued to an AIFM where that AIFM:

- (a) does not make use of the authorisation within 12 months, expressly renounces the authorisation or has ceased the activity covered by this Directive for the preceding 6 months, unless the Member State concerned has provided for authorisation to lapse in such cases;
- (b) obtained the authorisation by making false statements or by any other irregular means;
- (c) no longer meets the conditions under which authorisation was granted;
- (d) no longer complies with Directive 2006/49/EC if its authorisation also covers the discretionary portfolio management service referred to in point (a) of Article 6(4) of this Directive;
- (e) has seriously or systematically infringed the provisions adopted pursuant to this Directive; or
- (f) falls within any of the cases where national law, in respect of matters outside the scope of this Directive, provides for withdrawal.

CHAPTER III

OPERATING CONDITIONS FOR AIFMs

SECTION 1

General requirements

Article 12

General principles

1. Member States shall ensure that, at all times, AIFMs:

- (a) act honestly, with due skill, care and diligence and fairly in conducting their activities;
- (b) act in the best interests of the AIFs or the investors of the AIFs they manage and the integrity of the market;
- (c) have and employ effectively the resources and procedures that are necessary for the proper performance of their business activities;
- (d) take all reasonable steps to avoid conflicts of interest and, when they cannot be avoided, to identify, manage and monitor and, where applicable, disclose, those conflicts of interest in order to prevent them from adversely affecting the interests of the AIFs and their investors and to ensure that the AIFs they manage are fairly treated;
- (e) comply with all regulatory requirements applicable to the conduct of their business activities so as to promote the best interests of the AIFs or the investors of the AIFs they manage and the integrity of the market;
- (f) treat all AIF investors fairly.

No investor in an AIF shall obtain preferential treatment, unless such preferential treatment is disclosed in the relevant AIF's rules or instruments of incorporation.

2. Each AIFM the authorisation of which also covers the discretionary portfolio management service referred to in point (a) of Article 6(4) shall:

- (a) not be permitted to invest all or part of the client's portfolio in units or shares of the AIFs it manages, unless it receives prior general approval from the client;
- (b) with regard to the services referred to in Article 6(4), be subject to Directive 97/9/EC of the European Parliament and of the Council of 3 March 1997 on investor-compensation schemes ⁽¹⁾.

3. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying the criteria to be used by the relevant competent authorities to assess whether AIFMs comply with their obligations under paragraph 1.

⁽¹⁾ OJ L 84, 26.3.1997, p. 22.

*Article 13***Remuneration**

1. Member States shall require AIFMs to have remuneration policies and practices for those categories of staff, including senior management, risk takers, control functions, and any employees receiving total remuneration that takes them into the same remuneration bracket as senior management and risk takers, whose professional activities have a material impact on the risk profiles of the AIFMs or of the AIFs they manage, that are consistent with and promote sound and effective risk management and do not encourage risk-taking which is inconsistent with the risk profiles, rules or instruments of incorporation of the AIFs they manage.

The AIFMs shall determine the remuneration policies and practices in accordance with Annex II.

2. ESMA shall ensure the existence of guidelines on sound remuneration policies which comply with Annex II. The guidelines shall take into account the principles on sound remuneration policies set out in Recommendation 2009/384/EC, the size of the AIFMs and the size of AIFs they manage, their internal organisation and the nature, the scope and the complexity of their activities. ESMA shall cooperate closely with the European Supervisory Authority (European Banking Authority) (EBA).

*Article 14***Conflicts of interest**

1. Member States shall require AIFMs to take all reasonable steps to identify conflicts of interest that arise in the course of managing AIFs between:

- (a) the AIFM, including its managers, employees or any person directly or indirectly linked to the AIFM by control, and the AIF managed by the AIFM or the investors in that AIF;
- (b) the AIF or the investors in that AIF, and another AIF or the investors in that AIF;
- (c) the AIF or the investors in that AIF, and another client of the AIFM;
- (d) the AIF or the investors in that AIF, and a UCITS managed by the AIFM or the investors in that UCITS; or
- (e) two clients of the AIFM.

AIFMs shall maintain and operate effective organisational and administrative arrangements with a view to taking all reasonable steps designed to identify, prevent, manage and monitor conflicts of interest in order to prevent them from adversely affecting the interests of the AIFs and their investors.

AIFMs shall segregate, within their own operating environment, tasks and responsibilities which may be regarded as incompatible with each other or which may potentially generate systematic conflicts of interest. AIFMs shall assess whether their operating conditions may involve any other material conflicts of interest and disclose them to the investors of the AIFs.

2. Where organisational arrangements made by the AIFM to identify, prevent, manage and monitor conflicts of interest are not sufficient to ensure, with reasonable confidence, that risks of damage to investors' interests will be prevented, the AIFM shall clearly disclose the general nature or sources of conflicts of interest to the investors before undertaking business on their behalf, and develop appropriate policies and procedures.

3. Where the AIFM on behalf of an AIF uses the services of a prime broker, the terms shall be set out in a written contract. In particular any possibility of transfer and reuse of AIF assets shall be provided for in that contract and shall comply with the AIF rules or instruments of incorporation. The contract shall provide that the depositary be informed of the contract.

AIFMs shall exercise due skill, care and diligence in the selection and appointment of prime brokers with whom a contract is to be concluded.

4. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) the types of conflicts of interest as referred to in paragraph 1;
- (b) the reasonable steps AIFMs are expected to take in terms of structures and organisational and administrative procedures in order to identify, prevent, manage, monitor and disclose conflicts of interest.

*Article 15***Risk management**

1. AIFMs shall functionally and hierarchically separate the functions of risk management from the operating units, including from the functions of portfolio management.

The functional and hierarchical separation of the functions of risk management in accordance with the first subparagraph shall be reviewed by the competent authorities of the home Member State of the AIFM in accordance with the principle of proportionality, on the understanding that the AIFM shall, in any event, be able to demonstrate that specific safeguards against conflicts of interest allow for the independent performance of risk management activities and that the risk management process satisfies the requirements of this Article and is consistently effective.

2. AIFMs shall implement adequate risk management systems in order to identify, measure, manage and monitor appropriately all risks relevant to each AIF investment strategy and to which each AIF is or may be exposed.

AIFMs shall review the risk management systems with appropriate frequency at least once a year and adapt them whenever necessary.

3. AIFMs shall at least:

- (a) implement an appropriate, documented and regularly updated due diligence process when investing on behalf of the AIF, according to the investment strategy, the objectives and risk profile of the AIF;
- (b) ensure that the risks associated with each investment position of the AIF and their overall effect on the AIF's portfolio can be properly identified, measured, managed and monitored on an ongoing basis, including through the use of appropriate stress testing procedures;
- (c) ensure that the risk profile of the AIF shall correspond to the size, portfolio structure and investment strategies and objectives of the AIF as laid down in the AIF rules or instruments of incorporation, prospectus and offering documents.

4. AIFMs shall set a maximum level of leverage which they may employ on behalf of each AIF they manage as well as the extent of the right to reuse collateral or guarantee that could be granted under the leveraging arrangement, taking into account, inter alia:

- (a) the type of the AIF;
- (b) the investment strategy of the AIF;
- (c) the sources of leverage of the AIF;
- (d) any other interlinkage or relevant relationships with other financial services institutions, which could pose systemic risk;
- (e) the need to limit the exposure to any single counterparty;
- (f) the extent to which the leverage is collateralised;
- (g) the asset-liability ratio;

(h) the scale, nature and extent of the activity of the AIFM on the markets concerned.

5. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) the risk management systems to be employed by AIFMs in relation to the risks which they incur on behalf of the AIFs that they manage;
- (b) the appropriate frequency of review of the risk management system;
- (c) how the risk management function is to be functionally and hierarchically separated from the operating units, including the portfolio management function;
- (d) specific safeguards against conflicts of interest referred to in the second subparagraph of paragraph 1;
- (e) the requirements referred to in paragraph 3.

Article 16

Liquidity management

1. AIFMs shall, for each AIF that they manage which is not an unleveraged closed-ended AIF, employ an appropriate liquidity management system and adopt procedures which enable them to monitor the liquidity risk of the AIF and to ensure that the liquidity profile of the investments of the AIF complies with its underlying obligations.

AIFMs shall regularly conduct stress tests, under normal and exceptional liquidity conditions, which enable them to assess the liquidity risk of the AIFs and monitor the liquidity risk of the AIFs accordingly.

2. AIFMs shall ensure that, for each AIF that they manage, the investment strategy, the liquidity profile and the redemption policy are consistent.

3. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) the liquidity management systems and procedures; and
- (b) the alignment of the investment strategy, liquidity profile and redemption policy set out in paragraph 2.

*Article 17***Investment in securitisation positions**

In order to ensure cross-sectoral consistency and to remove misalignment between the interest of firms that repackage loans into tradable securities and originators within the meaning of point (41) of Article 4 of Directive 2006/48/EC, and AIFMs that invest in those securities or other financial instruments on behalf of AIFs, the Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures laying down the requirements in the following areas:

- (a) the requirements that need to be met by the originator, the sponsor or the original lender, in order for an AIFM to be allowed to invest in securities or other financial instruments of this type issued after 1 January 2011 on behalf of AIFs, including requirements that ensure that the originator, the sponsor or the original lender retains a net economic interest of not less than 5 %;
- (b) qualitative requirements that must be met by AIFMs which invest in these securities or other financial instruments on behalf of one or more AIFs.

SECTION 2

Organisational requirements*Article 18***General principles**

1. Member States shall require that AIFMs use, at all times, adequate and appropriate human and technical resources that are necessary for the proper management of AIFs.

In particular, the competent authorities of the home Member State of the AIFM, having regard also to the nature of the AIFs managed by the AIFM, shall require that the AIFM has sound administrative and accounting procedures, control and safeguard arrangements for electronic data processing and adequate internal control mechanisms including, in particular, rules for personal transactions by its employees or for the holding or management of investments in order to invest on its own account and ensuring, at least, that each transaction involving the AIFs may be reconstructed according to its origin, the parties to it, its nature, and the time and place at which it was effected and that the assets of the AIFs managed by the AIFM are invested in accordance with the AIF rules or instruments of incorporation and the legal provisions in force.

2. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying the procedures and arrangements as referred to in paragraph 1.

*Article 19***Valuation**

1. AIFMs shall ensure that, for each AIF that they manage, appropriate and consistent procedures are established so that a proper and independent valuation of the assets of the AIF can be performed in accordance with this Article, the applicable national law and the AIF rules or instruments of incorporation.

2. The rules applicable to the valuation of assets and the calculation of the net asset value per unit or share of the AIF shall be laid down in the law of the country where the AIF is established and/or in the AIF rules or instruments of incorporation.

3. AIFMs shall also ensure that the net asset value per unit or share of AIFs is calculated and disclosed to the investors in accordance with this Article, the applicable national law and the AIF rules or instruments of incorporation.

The valuation procedures used shall ensure that the assets are valued and the net asset value per unit or share is calculated at least once a year.

If the AIF is of the open-ended type, such valuations and calculations shall also be carried out at a frequency which is both appropriate to the assets held by the AIF and its issuance and redemption frequency.

If the AIF is of the closed-ended type, such valuations and calculations shall also be carried out in case of an increase or decrease of the capital by the relevant AIF.

The investors shall be informed of the valuations and calculations as set out in the relevant AIF rules or instruments of incorporation.

4. AIFMs shall ensure that the valuation function is either performed by:

- (a) an external valuer, being a legal or natural person independent from the AIF, the AIFM and any other persons with close links to the AIF or the AIFM; or
- (b) the AIFM itself, provided that the valuation task is functionally independent from the portfolio management and the remuneration policy and other measures ensure that conflicts of interest are mitigated and that undue influence upon the employees is prevented.

The depositary appointed for an AIF shall not be appointed as external valuer of that AIF, unless it has functionally and hierarchically separated the performance of its depositary functions from its tasks as external valuer and the potential conflicts of interest are properly identified, managed, monitored and disclosed to the investors of the AIF.

5. Where an external valuer performs the valuation function, the AIFM shall demonstrate that:

- (a) the external valuer is subject to mandatory professional registration recognised by law or to legal or regulatory provisions or rules of professional conduct;
- (b) the external valuer can provide sufficient professional guarantees to be able to perform effectively the relevant valuation function in accordance with paragraphs 1, 2 and 3; and
- (c) the appointment of the external valuer complies with the requirements of Article 20(1) and (2) and the delegated acts adopted pursuant to Article 20(7).

6. The appointed external valuer shall not delegate the valuation function to a third party.

7. AIFMs shall notify the appointment of the external valuer to the competent authorities of their home Member State which may require that another external valuer be appointed instead, where the conditions laid down in paragraph 5 are not met.

8. The valuation shall be performed impartially and with all due skill, care and diligence.

9. Where the valuation function is not performed by an independent external valuer, the competent authorities of the home Member State of the AIFM may require the AIFM to have its valuation procedures and/or valuations verified by an external valuer or, where appropriate, by an auditor.

10. AIFMs are responsible for the proper valuation of AIF assets, the calculation of the net asset value and the publication of that net asset value. The AIFM's liability towards the AIF and its investors shall, therefore, not be affected by the fact that the AIFM has appointed an external valuer.

Notwithstanding the first subparagraph and irrespective of any contractual arrangements providing otherwise, the external valuer shall be liable to the AIFM for any losses suffered by the AIFM as a result of the external valuer's negligence or intentional failure to perform its tasks.

11. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) the criteria concerning the procedures for the proper valuation of the assets and the calculation of the net asset value per unit or share;
- (b) the professional guarantees the external valuer must be able to provide to effectively perform the valuation function;

- (c) the frequency of valuation carried out by open-ended AIFs which is both appropriate to the assets held by the AIF and its issuance and redemption policy.

SECTION 3

Delegation of AIFM functions

Article 20

Delegation

1. AIFMs which intend to delegate to third parties the task of carrying out functions on their behalf shall notify the competent authorities of their home Member State before the delegation arrangements become effective. The following conditions shall be met:

- (a) the AIFM must be able to justify its entire delegation structure on objective reasons;
- (b) the delegate must dispose of sufficient resources to perform the respective tasks and the persons who effectively conduct the business of the delegate must be of sufficiently good repute and sufficiently experienced;
- (c) where the delegation concerns portfolio management or risk management, it must be conferred only on undertakings which are authorised or registered for the purpose of asset management and subject to supervision or, where that condition cannot be met, only subject to prior approval by the competent authorities of the home Member State of the AIFM;
- (d) where the delegation concerns portfolio management or risk management and is conferred on a third-country undertaking, in addition to the requirements in point (c), cooperation between the competent authorities of the home Member State of the AIFM and the supervisory authority of the undertaking must be ensured;
- (e) the delegation must not prevent the effectiveness of supervision of the AIFM, and, in particular, must not prevent the AIFM from acting, or the AIF from being managed, in the best interests of its investors;
- (f) the AIFM must be able to demonstrate that the delegate is qualified and capable of undertaking the functions in question, that it was selected with all due care and that the AIFM is in a position to monitor effectively at any time the delegated activity, to give at any time further instructions to the delegate and to withdraw the delegation with immediate effect when this is in the interest of investors.

The AIFM shall review the services provided by each delegate on an ongoing basis.

2. No delegation of portfolio management or risk management shall be conferred on:

- (a) the depositary or a delegate of the depositary; or
- (b) any other entity whose interests may conflict with those of the AIFM or the investors of the AIF, unless such entity has functionally and hierarchically separated the performance of its portfolio management or risk management tasks from its other potentially conflicting tasks, and the potential conflicts of interest are properly identified, managed, monitored and disclosed to the investors of the AIF.

3. The AIFM's liability towards the AIF and its investors shall not be affected by the fact that the AIFM has delegated functions to a third party, or by any further sub-delegation, nor shall the AIFM delegate its functions to the extent that, in essence, it can no longer be considered to be the manager of the AIF and to the extent that it becomes a letter-box entity.

4. The third party may sub-delegate any of the functions delegated to it provided that the following conditions are met:

- (a) the AIFM consented prior to the sub-delegation;
- (b) the AIFM notified the competent authorities of its home Member State before the sub-delegation arrangements become effective;
- (c) the conditions set out in paragraph 1, on the understanding that all references to the 'delegate' are read as references to the 'sub-delegate'.

5. No sub-delegation of portfolio management or risk management shall be conferred on:

- (a) the depositary or a delegate of the depositary; or
- (b) any other entity whose interests may conflict with those of the AIFM or the investors of the AIF, unless such entity has functionally and hierarchically separated the performance of its portfolio management or risk management tasks from its other potentially conflicting tasks, and the potential conflicts of interest are properly identified, managed, monitored and disclosed to the investors of the AIF.

The relevant delegate shall review the services provided by each sub-delegate on an ongoing basis.

6. Where the sub-delegate further delegates any of the functions delegated to it, the conditions set out in paragraph 4 shall apply *mutatis mutandis*.

7. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) the conditions for fulfilling the requirements set out in paragraphs 1, 2, 4 and 5;
- (b) the conditions under which the AIFM shall be deemed to have delegated its functions to the extent that it becomes a letter-box entity and can no longer be considered to be the manager of the AIF as set out in paragraph 3.

SECTION 4

Depositary

Article 21

Depositary

1. For each AIF it manages, the AIFM shall ensure that a single depositary is appointed in accordance with this Article.

2. The appointment of the depositary shall be evidenced by written contract. The contract shall, *inter alia*, regulate the flow of information deemed necessary to allow the depositary to perform its functions for the AIF for which it has been appointed as depositary, as set out in this Directive and in other relevant laws, regulations or administrative provisions.

3. The depositary shall be:

- (a) a credit institution having its registered office in the Union and authorised in accordance with Directive 2006/48/EC;
- (b) an investment firm having its registered office in the Union, subject to capital adequacy requirements in accordance with Article 20(1) of Directive 2006/49/EC including capital requirements for operational risks and authorised in accordance with Directive 2004/39/EC and which also provides the ancillary service of safe-keeping and administration of financial instruments for the account of clients in accordance with point (1) of Section B of Annex I to Directive 2004/39/EC; such investment firms shall in any case have own funds not less than the amount of initial capital referred to in Article 9 of Directive 2006/49/EC; or
- (c) another category of institution that is subject to prudential regulation and ongoing supervision and which, on 21 July 2011, falls within the categories of institution determined by Member States to be eligible to be a depositary under Article 23(3) of Directive 2009/65/EC.

For non-EU AIFs only, and without prejudice to point (b) of paragraph 5, the depositary may also be a credit institution or any other entity of the same nature as the entities referred to in points (a) and (b) of the first subparagraph of this paragraph provided that the conditions in point (b) of paragraph 6 are met.

In addition, Member States may allow that in relation to AIFs which have no redemption rights exercisable during the period of 5 years from the date of the initial investments and which, in accordance with their core investment policy, generally do not invest in assets that must be held in custody in accordance with point (a) of paragraph 8 or generally invest in issuers or non-listed companies in order to potentially acquire control over such companies in accordance with Article 26, the depositary may be an entity which carries out depositary functions as part of its professional or business activities in respect of which such entity is subject to mandatory professional registration recognised by law or to legal or regulatory provisions or rules of professional conduct and which can provide sufficient financial and professional guarantees to enable it to perform effectively the relevant depositary functions and meet the commitments inherent in those functions.

4. In order to avoid conflicts of interest between the depositary, the AIFM and/or the AIF and/or its investors:

- (a) an AIFM shall not act as depositary;
- (b) a prime broker acting as counterparty to an AIF shall not act as depositary for that AIF, unless it has functionally and hierarchically separated the performance of its depositary functions from its tasks as prime broker and the potential conflicts of interest are properly identified, managed, monitored and disclosed to the investors of the AIF. Delegation by the depositary to such prime broker of its custody tasks in accordance with paragraph 11 is allowed if the relevant conditions are met.

5. The depositary shall be established in one of the following locations:

- (a) for EU AIFs, in the home Member State of the AIF;
- (b) for non-EU AIFs, in the third country where the AIF is established or in the home Member State of the AIFM managing the AIF or in the Member State of reference of the AIFM managing the AIF.

6. Without prejudice to the requirements set out in paragraph 3, the appointment of a depositary established in a third country shall, at all times, be subject to the following conditions:

- (a) the competent authorities of the Member States in which the units or shares of the non-EU AIF are intended to be marketed, and, in so far as different, of the home Member State of the AIFM, have signed cooperation and exchange of information arrangements with the competent authorities of the depositary;

- (b) the depositary is subject to effective prudential regulation, including minimum capital requirements, and supervision which have the same effect as Union law and are effectively enforced;

- (c) the third country where the depositary is established is not listed as a Non-Cooperative Country and Territory by FATF;

- (d) the Member States in which the units or shares of the non-EU AIF are intended to be marketed, and, in so far as different, the home Member State of the AIFM, have signed an agreement with the third country where the depositary is established which fully complies with the standards laid down in Article 26 of the OECD Model Tax Convention on Income and on Capital and ensures an effective exchange of information in tax matters including any multilateral tax agreements;

- (e) the depositary shall by contract be liable to the AIF or to the investors of the AIF, consistently with paragraphs 12 and 13, and shall expressly agree to comply with paragraph 11.

Where a competent authority of another Member State disagrees with the assessment made on the application of points (a), (c) or (e) of the first subparagraph by the competent authorities of the home Member State of the AIFM, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

On the basis of the criteria referred to in point (b) of paragraph 17, the Commission shall adopt implementing acts, stating that prudential regulation and supervision of a third country have the same effect as Union law and are effectively enforced. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 59(2).

7. The depositary shall in general ensure that the AIF's cash flows are properly monitored, and shall in particular ensure that all payments made by or on behalf of investors upon the subscription of units or shares of an AIF have been received and that all cash of the AIF has been booked in cash accounts opened in the name of the AIF or in the name of the AIFM acting on behalf of the AIF or in the name of the depositary acting on behalf of the AIF at an entity referred to in points (a), (b) and (c) of Article 18(1) of Directive 2006/73/EC, or another entity of the same nature, in the relevant market where cash accounts are required provided that such entity is subject to effective prudential regulation and supervision which have the same effect as Union law and are effectively enforced and in accordance with the principles set out in Article 16 of Directive 2006/73/EC.

Where the cash accounts are opened in the name of the depositary acting on behalf of the AIF, no cash of the entity referred to in the first subparagraph and none of the depositary's own cash shall be booked on such accounts.

8. The assets of the AIF or the AIFM acting on behalf of the AIF shall be entrusted to the depositary for safe-keeping, as follows:

- (a) for financial instruments that can be held in custody:
 - (i) the depositary shall hold in custody all financial instruments that can be registered in a financial instruments account opened in the depositary's books and all financial instruments that can be physically delivered to the depositary;
 - (ii) for that purpose, the depositary shall ensure that all those financial instruments that can be registered in a financial instruments account opened in the depositary's books are registered in the depositary's books within segregated accounts in accordance with the principles set out in Article 16 of Directive 2006/73/EC, opened in the name of the AIF or the AIFM acting on behalf of the AIF, so that they can be clearly identified as belonging to the AIF in accordance with the applicable law at all times;
- (b) for other assets:
 - (i) the depositary shall verify the ownership of the AIF or the AIFM acting on behalf of the AIF of such assets and shall maintain a record of those assets for which it is satisfied that the AIF or the AIFM acting on behalf of the AIF holds the ownership of such assets;
 - (ii) the assessment whether the AIF or the AIFM acting on behalf of the AIF holds the ownership shall be based on information or documents provided by the AIF or the AIFM and, where available, on external evidence;
 - (iii) the depositary shall keep its record up-to-date.

9. In addition to the tasks referred to in paragraphs 7 and 8, the depositary shall:

- (a) ensure that the sale, issue, re-purchase, redemption and cancellation of units or shares of the AIF are carried out in accordance with the applicable national law and the AIF rules or instruments of incorporation;
- (b) ensure that the value of the units or shares of the AIF is calculated in accordance with the applicable national law, the AIF rules or instruments of incorporation and the procedures laid down in Article 19;
- (c) carry out the instructions of the AIFM, unless they conflict with the applicable national law or the AIF rules or instruments of incorporation;

(d) ensure that in transactions involving the AIF's assets any consideration is remitted to the AIF within the usual time limits;

(e) ensure that an AIF's income is applied in accordance with the applicable national law and the AIF rules or instruments of incorporation.

10. In the context of their respective roles, the AIFM and the depositary shall act honestly, fairly, professionally, independently and in the interest of the AIF and the investors of the AIF.

A depositary shall not carry out activities with regard to the AIF or the AIFM on behalf of the AIF that may create conflicts of interest between the AIF, the investors in the AIF, the AIFM and itself, unless the depositary has functionally and hierarchically separated the performance of its depositary tasks from its other potentially conflicting tasks, and the potential conflicts of interest are properly identified, managed, monitored and disclosed to the investors of the AIF.

The assets referred to in paragraph 8 shall not be reused by the depositary without the prior consent of the AIF or the AIFM acting on behalf of the AIF.

11. The depositary shall not delegate to third parties its functions as described in this Article, save for those referred to in paragraph 8.

The depositary may delegate to third parties the functions referred to in paragraph 8 subject to the following conditions:

- (a) the tasks are not delegated with the intention of avoiding the requirements of this Directive;
- (b) the depositary can demonstrate that there is an objective reason for the delegation;
- (c) the depositary has exercised all due skill, care and diligence in the selection and the appointment of any third party to whom it wants to delegate parts of its tasks, and keeps exercising all due skill, care and diligence in the periodic review and ongoing monitoring of any third party to whom it has delegated parts of its tasks and of the arrangements of the third party in respect of the matters delegated to it; and
- (d) the depositary ensures that the third party meets the following conditions at all times during the performance of the tasks delegated to it:
 - (i) the third party has the structures and the expertise that are adequate and proportionate to the nature and complexity of the assets of the AIF or the AIFM acting on behalf of the AIF which have been entrusted to it;

- (ii) for custody tasks referred to in point (a) of paragraph 8, the third party is subject to effective prudential regulation, including minimum capital requirements, and supervision in the jurisdiction concerned and the third party is subject to an external periodic audit to ensure that the financial instruments are in its possession;
- (iii) the third party segregates the assets of the depositary's clients from its own assets and from the assets of the depositary in such a way that they can at any time be clearly identified as belonging to clients of a particular depositary;
- (iv) the third party does not make use of the assets without the prior consent of the AIF or the AIFM acting on behalf of the AIF and prior notification to the depositary; and
- (v) the third party complies with the general obligations and prohibitions set out in paragraphs 8 and 10.

Notwithstanding point (d)(ii) of the second subparagraph, where the law of a third country requires that certain financial instruments be held in custody by a local entity and no local entities satisfy the delegation requirements laid down in that point, the depositary may delegate its functions to such a local entity only to the extent required by the law of the third country and only for as long as there are no local entities that satisfy the delegation requirements, subject to the following requirements:

- (a) the investors of the relevant AIF must be duly informed that such delegation is required due to legal constraints in the law of the third country and of the circumstances justifying the delegation, prior to their investment; and
- (b) the AIF, or the AIFM on behalf of the AIF, must instruct the depositary to delegate the custody of such financial instruments to such local entity.

The third party may, in turn, sub-delegate those functions, subject to the same requirements. In such a case, paragraph 13 shall apply *mutatis mutandis* to the relevant parties.

For the purposes of this paragraph, the provision of services as specified by Directive 98/26/EC by securities settlement systems as designated for the purposes of that Directive or the provision of similar services by third-country securities settlement systems shall not be considered a delegation of its custody functions.

12. The depositary shall be liable to the AIF or to the investors of the AIF, for the loss by the depositary or a third party to whom the custody of financial instruments held in custody in accordance with point (a) of paragraph 8 has been delegated.

In the case of such a loss of a financial instrument held in custody, the depositary shall return a financial instrument of identical type or the corresponding amount to the AIF or the AIFM acting on behalf of the AIF without undue delay. The depositary shall not be liable if it can prove that the loss has arisen as a result of an external event beyond its reasonable control, the consequences of which would have been unavoidable despite all reasonable efforts to the contrary.

The depositary shall also be liable to the AIF, or to the investors of the AIF, for all other losses suffered by them as a result of the depositary's negligent or intentional failure to properly fulfil its obligations pursuant to this Directive.

13. The depositary's liability shall not be affected by any delegation referred to in paragraph 11.

Notwithstanding the first subparagraph of this paragraph, in case of a loss of financial instruments held in custody by a third party pursuant to paragraph 11, the depositary may discharge itself of liability if it can prove that:

- (a) all requirements for the delegation of its custody tasks set out in the second subparagraph of paragraph 11 are met;
- (b) a written contract between the depositary and the third party expressly transfers the liability of the depositary to that third party and makes it possible for the AIF or the AIFM acting on behalf of the AIF to make a claim against the third party in respect of the loss of financial instruments or for the depositary to make such a claim on their behalf; and
- (c) a written contract between the depositary and the AIF or the AIFM acting on behalf of the AIF, expressly allows a discharge of the depositary's liability and establishes the objective reason to contract such a discharge.

14. Further, where the law of a third country requires that certain financial instruments are held in custody by a local entity and there are no local entities that satisfy the delegation requirements laid down in point (d)(ii) of paragraph 11, the depositary can discharge itself of liability provided that the following conditions are met:

- (a) the rules or instruments of incorporation of the AIF concerned expressly allow for such a discharge under the conditions set out in this paragraph;
- (b) the investors of the relevant AIF have been duly informed of that discharge and of the circumstances justifying the discharge prior to their investment;
- (c) the AIF or the AIFM on behalf of the AIF instructed the depositary to delegate the custody of such financial instruments to a local entity;

- (d) there is a written contract between the depositary and the AIF or the AIFM acting on behalf of the AIF, which expressly allows such a discharge; and
- (e) there is a written contract between the depositary and the third party that expressly transfers the liability of the depositary to that local entity and makes it possible for the AIF or the AIFM acting on behalf of the AIF to make a claim against that local entity in respect of the loss of financial instruments or for the depositary to make such a claim on their behalf.

15. Liability to the investors of the AIF may be invoked directly or indirectly through the AIFM, depending on the legal nature of the relationship between the depositary, the AIFM and the investors.

16. The depositary shall make available to its competent authorities, on request, all information which it has obtained while performing its duties and that may be necessary for the competent authorities of the AIF or the AIFM. If the competent authorities of the AIF or the AIFM are different from those of the depositary, the competent authorities of the depositary shall share the information received without delay with the competent authorities of the AIF and the AIFM.

17. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) the particulars that need to be included in the written contract referred to in paragraph 2;
- (b) general criteria for assessing whether the prudential regulation and supervision of third countries as referred to in point (b) of paragraph 6 have the same effect as Union law and are effectively enforced;
- (c) the conditions for performing the depositary functions pursuant to paragraphs 7, 8 and 9, including:
- (i) the type of financial instruments to be included in the scope of the depositary's custody duties in accordance with point (a) of paragraph 8;
 - (ii) the conditions subject to which the depositary is able to exercise its custody duties over financial instruments registered with a central depositary; and
 - (iii) the conditions subject to which the depositary is to safekeep the financial instruments issued in a nominative form and registered with an issuer or a registrar, in accordance with point (b) of paragraph 8;
- (d) the due diligence duties of depositaries pursuant to point (c) of paragraph 11;

- (e) the segregation obligation pursuant to point (d)(iii) of paragraph 11;
- (f) the conditions subject to which and circumstances in which financial instruments held in custody are to be considered as lost;
- (g) what is to be understood by external events beyond reasonable control, the consequences of which would have been unavoidable despite all reasonable efforts to the contrary pursuant to paragraph 12;
- (h) the conditions subject to which and circumstances in which there is an objective reason to contract a discharge pursuant to paragraph 13.

CHAPTER IV

TRANSPARENCY REQUIREMENTS

Article 22

Annual report

1. An AIFM shall, for each of the EU AIFs it manages and for each of the AIFs it markets in the Union, make available an annual report for each financial year no later than 6 months following the end of the financial year. The annual report shall be provided to investors on request. The annual report shall be made available to the competent authorities of the home Member State of the AIFM, and, where applicable, the home Member State of the AIF.

Where the AIF is required to make public an annual financial report in accordance with Directive 2004/109/EC only such additional information referred to in paragraph 2 needs to be provided to investors on request, either separately or as an additional part of the annual financial report. In the latter case the annual financial report shall be made public no later than 4 months following the end of the financial year.

2. The annual report shall at least contain the following:

- (a) a balance-sheet or a statement of assets and liabilities;
- (b) an income and expenditure account for the financial year;
- (c) a report on the activities of the financial year;
- (d) any material changes in the information listed in Article 23 during the financial year covered by the report;
- (e) the total amount of remuneration for the financial year, split into fixed and variable remuneration, paid by the AIFM to its staff, and number of beneficiaries, and, where relevant, carried interest paid by the AIF;

(f) the aggregate amount of remuneration broken down by senior management and members of staff of the AIFM whose actions have a material impact on the risk profile of the AIF.

3. The accounting information given in the annual report shall be prepared in accordance with the accounting standards of the home Member State of the AIF or in accordance with the accounting standards of the third country where the AIF is established and with the accounting rules laid down in the AIF rules or instruments of incorporation.

The accounting information given in the annual report shall be audited by one or more persons empowered by law to audit accounts in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts⁽¹⁾. The auditor's report, including any qualifications, shall be reproduced in full in the annual report.

By way of derogation from the second subparagraph, Member States may permit AIFMs marketing non-EU AIFs to subject the annual reports of those AIFs to an audit meeting international auditing standards in force in the country where the AIF has its registered office.

4. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying the content and format of the annual report. Those measures shall be adapted to the type of AIF to which they apply.

Article 23

Disclosure to investors

1. AIFMs shall for each of the EU AIFs that they manage and for each of the AIFs that they market in the Union make available to AIF investors, in accordance with the AIF rules or instruments of incorporation, the following information before they invest in the AIF, as well as any material changes thereof:

(a) a description of the investment strategy and objectives of the AIF, information on where any master AIF is established and where the underlying funds are established if the AIF is a fund of funds, a description of the types of assets in which the AIF may invest, the techniques it may employ and all associated risks, any applicable investment restrictions, the circumstances in which the AIF may use leverage, the types and sources of leverage permitted and the associated risks, any restrictions on the use of leverage and any collateral and asset reuse arrangements, and the maximum level of leverage which the AIFM are entitled to employ on behalf of the AIF;

(b) a description of the procedures by which the AIF may change its investment strategy or investment policy, or both;

(c) a description of the main legal implications of the contractual relationship entered into for the purpose of investment, including information on jurisdiction, on the applicable law and on the existence or not of any legal instruments providing for the recognition and enforcement of judgments in the territory where the AIF is established;

(d) the identity of the AIFM, the AIF's depositary, auditor and any other service providers and a description of their duties and the investors' rights;

(e) a description of how the AIFM is complying with the requirements of Article 9(7);

(f) a description of any delegated management function as referred to in Annex I by the AIFM and of any safe-keeping function delegated by the depositary, the identification of the delegate and any conflicts of interest that may arise from such delegations;

(g) a description of the AIF's valuation procedure and of the pricing methodology for valuing assets, including the methods used in valuing hard-to-value assets in accordance with Article 19;

(h) a description of the AIF's liquidity risk management, including the redemption rights both in normal and in exceptional circumstances, and the existing redemption arrangements with investors;

(i) a description of all fees, charges and expenses and of the maximum amounts thereof which are directly or indirectly borne by investors;

(j) a description of how the AIFM ensures a fair treatment of investors and, whenever an investor obtains preferential treatment or the right to obtain preferential treatment, a description of that preferential treatment, the type of investors who obtain such preferential treatment and, where relevant, their legal or economic links with the AIF or AIFM;

(k) the latest annual report referred to in Article 22;

(l) the procedure and conditions for the issue and sale of units or shares;

(m) the latest net asset value of the AIF or the latest market price of the unit or share of the AIF, in accordance with Article 19;

(n) where available, the historical performance of the AIF;

⁽¹⁾ OJ L 157, 9.6.2006, p. 87.

(o) the identity of the prime broker and a description of any material arrangements of the AIF with its prime brokers and the way the conflicts of interest in relation thereto are managed and the provision in the contract with the depositary on the possibility of transfer and reuse of AIF assets, and information about any transfer of liability to the prime broker that may exist;

(p) a description of how and when the information required under paragraphs 4 and 5 will be disclosed.

2. The AIFM shall inform the investors before they invest in the AIF of any arrangement made by the depositary to contractually discharge itself of liability in accordance with Article 21(13). The AIFM shall also inform investors of any changes with respect to depositary liability without delay.

3. Where the AIF is required to publish a prospectus in accordance with Directive 2003/71/EC or in accordance with national law, only such information referred to in paragraphs 1 and 2 which is in addition to that contained in the prospectus needs to be disclosed separately or as additional information in the prospectus.

4. AIFMs shall, for each of the EU AIFs that they manage and for each of the AIFs that they market in the Union, periodically disclose to investors:

(a) the percentage of the AIF's assets which are subject to special arrangements arising from their illiquid nature;

(b) any new arrangements for managing the liquidity of the AIF;

(c) the current risk profile of the AIF and the risk management systems employed by the AIFM to manage those risks.

5. AIFMs managing EU AIFs employing leverage or marketing in the Union AIFs employing leverage shall, for each such AIF disclose, on a regular basis:

(a) any changes to the maximum level of leverage which the AIFM may employ on behalf of the AIF as well as any right of the reuse of collateral or any guarantee granted under the leveraging arrangement;

(b) the total amount of leverage employed by that AIF.

6. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying the disclosure obli-

gations of AIFMs referred to in paragraphs 4 and 5, including the frequency of the disclosure referred to in paragraph 5. Those measures shall be adapted to the type of AIFM to which they apply.

Article 24

Reporting obligations to competent authorities

1. An AIFM shall regularly report to the competent authorities of its home Member State on the principal markets and instruments in which it trades on behalf of the AIFs it manages.

It shall provide information on the main instruments in which it is trading, on markets of which it is a member or where it actively trades, and on the principal exposures and most important concentrations of each of the AIFs it manages.

2. An AIFM shall, for each of the EU AIFs it manages and for each of the AIFs it markets in the Union, provide the following to the competent authorities of its home Member State:

(a) the percentage of the AIF's assets which are subject to special arrangements arising from their illiquid nature;

(b) any new arrangements for managing the liquidity of the AIF;

(c) the current risk profile of the AIF and the risk management systems employed by the AIFM to manage the market risk, liquidity risk, counterparty risk and other risks including operational risk;

(d) information on the main categories of assets in which the AIF invested; and

(e) the results of the stress tests performed in accordance with point (b) of Article 15(3) and the second subparagraph of Article 16(1).

3. The AIFM shall, on request, provide the following documents to the competent authorities of its home Member State:

(a) an annual report of each EU AIF managed by the AIFM and of each AIF marketed by it in the Union, for each financial year, in accordance with Article 22(1);

(b) for the end of each quarter a detailed list of all AIFs which the AIFM manages.

4. An AIFM managing AIFs employing leverage on a substantial basis shall make available information about the overall level of leverage employed by each AIF it manages, a break-down between leverage arising from borrowing of cash or securities and leverage embedded in financial derivatives and the extent to which the AIF's assets have been reused under leveraging arrangements to the competent authorities of its home Member State.

That information shall include the identity of the five largest sources of borrowed cash or securities for each of the AIFs managed by the AIFM, and the amounts of leverage received from each of those sources for each of those AIFs.

For non-EU AIFMs, the reporting obligations referred to in this paragraph are limited to EU AIFs managed by them and non-EU AIFs marketed by them in the Union.

5. Where necessary for the effective monitoring of systemic risk, the competent authorities of the home Member State may require information in addition to that described in this Article, on a periodic as well as on an ad-hoc basis. The competent authorities shall inform ESMA about the additional information requirements.

In exceptional circumstances and where required in order to ensure the stability and integrity of the financial system, or to promote long-term sustainable growth, ESMA may request the competent authorities of the home Member State to impose additional reporting requirements.

6. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying:

- (a) when leverage is to be considered to be employed on a substantial basis for the purposes of paragraph 4; and
- (b) the obligations to report and provide information provided for in this Article.

Those measures shall take into account the need to avoid an excessive administrative burden on competent authorities.

CHAPTER V

AIFMs MANAGING SPECIFIC TYPES OF AIF

SECTION 1

AIFMs managing leveraged AIFs

Article 25

Use of information by competent authorities, supervisory cooperation and limits to leverage

1. Member States shall ensure that the competent authorities of the home Member State of the AIFM use the information to be gathered under Article 24 for the purposes of identifying the extent to which the use of leverage contributes to the build-up of systemic risk in the financial system, risks of disorderly markets or risks to the long-term growth of the economy.

2. The competent authorities of the home Member State of the AIFM shall ensure that all information gathered under Article 24 in respect of all AIFMs that they supervise and the information gathered under Article 7 is made available to competent authorities of other relevant Member States, ESMA and the ESRB by means of the procedures set out in Article 50 on supervisory cooperation. They shall, without delay, also provide information by means of those procedures, and bilaterally to the competent authorities of other Member States directly concerned, if an AIFM under their responsibility, or AIF managed by that AIFM could potentially constitute an important source of counterparty risk to a credit institution or other systemically relevant institutions in other Member States.

3. The AIFM shall demonstrate that the leverage limits set by it for each AIF it manages are reasonable and that it complies with those limits at all times. The competent authorities shall assess the risks that the use of leverage by an AIFM with respect to the AIFs it manages could entail, and, where deemed necessary in order to ensure the stability and integrity of the financial system, the competent authorities of the home Member State of the AIFM, after having notified ESMA, the ESRB and the competent authorities of the relevant AIF, shall impose limits to the level of leverage that an AIFM are entitled to employ or other restrictions on the management of the AIF with respect to the AIFs under its management to limit the extent to which the use of leverage contributes to the build up of systemic risk in the financial system or risks of disorderly markets. The competent authorities of the home Member State of the AIFM shall duly inform ESMA, the ESRB and the competent authorities of the AIF, of actions taken in this respect, through the procedures set out in Article 50.

4. The notification referred to in paragraph 3 shall be made not less than 10 working days before the proposed measure is intended to take effect or to be renewed. The notification shall include details of the proposed measure, the reasons for the measure and when the measure is intended to take effect. In exceptional circumstances, the competent authorities of the home Member State of the AIFM may decide that the proposed measure takes effect within the period referred to in the first sentence.

5. ESMA shall perform a facilitation and coordination role, and, in particular, shall try to ensure that a consistent approach is taken by competent authorities, in relation to measures proposed by competent authorities under paragraph 3.

6. After receiving the notification referred to in paragraph 3, ESMA shall issue advice to the competent authorities of the home Member State of the AIFM about the measure that is proposed or taken. The advice may, in particular, address whether the conditions for taking action appear to be met, whether the measures are appropriate and the duration of the measures.

7. On the basis of the information received in accordance with paragraph 2, and after taking into account any advice of the ESRB, ESMA may determine that the leverage employed by an AIFM, or by a group of AIFMs, poses a substantial risk to the stability and integrity of the financial system and may issue advice to competent authorities specifying the remedial measures to be taken, including limits to the level of leverage, which that AIFM, or that group of AIFMs, are entitled to employ. ESMA shall immediately inform the competent authorities concerned, the ESRB and the Commission of any such determination.

8. If a competent authority proposes to take action contrary to ESMA's advice referred to in paragraph 6 or 7 it shall inform ESMA, stating its reasons. ESMA may publish the fact that a competent authority does not comply or intend to comply with its advice. ESMA may also decide, on a case-by-case basis, to publish the reasons provided by the competent authority for not complying with its advice. The competent authorities concerned shall receive advance notice about such a publication.

9. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures setting out principles specifying the circumstances in which competent authorities apply the provisions set out in paragraph 3, taking into account different strategies of AIFs, different market conditions in which AIFs operate and possible pro-cyclical effects of applying those provisions.

SECTION 2

Obligations for AIFMs managing AIFs which acquire control of non-listed companies and issuers

Article 26

Scope

1. This Section shall apply to the following:

- (a) AIFMs managing one or more AIFs which either individually or jointly on the basis of an agreement aimed at acquiring control, acquire control of a non-listed company in accordance with paragraph 5;

- (b) AIFMs cooperating with one or more other AIFMs on the basis of an agreement pursuant to which the AIFs managed by those AIFMs jointly, acquire control of a non-listed company in accordance with paragraph 5.

2. This Section shall not apply where the non-listed companies concerned are:

- (a) small and medium-sized enterprises within the meaning of Article 2(1) of the Annex to Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ⁽¹⁾; or
- (b) special purpose vehicles with the purpose of purchasing, holding or administering real estate.

3. Without prejudice to paragraphs 1 and 2 of this Article, Article 27(1) shall also apply to AIFMs managing AIFs that acquire a non-controlling participation in a non-listed company.

4. Article 28(1), (2) and (3) and Article 30 shall apply also to AIFMs managing AIFs that acquire control over issuers. For the purposes of those Articles, paragraphs 1 and 2 of this Article shall apply *mutatis mutandis*.

5. For the purpose of this Section, for non-listed companies, control shall mean more than 50 % of the voting rights of the companies.

When calculating the percentage of voting rights held by the relevant AIF, in addition to the voting rights held directly by the relevant AIF, the voting rights of the following shall be taken into account, subject to control as referred to in the first subparagraph being established:

- (a) an undertaking controlled by the AIF; and
- (b) a natural or legal person acting in its own name but on behalf of the AIF or on behalf of an undertaking controlled by the AIF.

The percentage of voting rights shall be calculated on the basis of all the shares to which voting rights are attached even if the exercise thereof is suspended.

Notwithstanding point (i) of Article 4(1), for the purpose of Article 28(1), (2) and (3) and Article 30 in regard to issuers control shall be determined in accordance with Article 5(3) of Directive 2004/25/EC.

6. This Section shall apply subject to the conditions and restrictions set out in Article 6 of Directive 2002/14/EC.

⁽¹⁾ OJ L 124, 20.5.2003, p. 36.

7. This Section shall apply without prejudice to any stricter rules adopted by Member States with respect to the acquisition of holdings in issuers and non-listed companies in their territories.

Article 27

Notification of the acquisition of major holdings and control of non-listed companies

1. Member States shall require that when an AIF acquires, disposes of or holds shares of a non-listed company, the AIFM managing such an AIF notify the competent authorities of its home Member State of the proportion of voting rights of the non-listed company held by the AIF any time when that proportion reaches, exceeds or falls below the thresholds of 10 %, 20 %, 30 %, 50 % and 75 %.

2. Member States shall require that when an AIF acquires, individually or jointly, control over a non-listed company pursuant to Article 26(1), in conjunction with paragraph 5 of that Article, the AIFM managing such an AIF notify the following of the acquisition of control by the AIF:

- (a) the non-listed company;
- (b) the shareholders of which the identities and addresses are available to the AIFM or can be made available by the non-listed company or through a register to which the AIFM has or can obtain access; and
- (c) the competent authorities of the home Member State of the AIFM.

3. The notification required under paragraph 2 shall contain the following additional information:

- (a) the resulting situation in terms of voting rights;
- (b) the conditions subject to which control was acquired, including information about the identity of the different shareholders involved, any natural person or legal entity entitled to exercise voting rights on their behalf and, if applicable, the chain of undertakings through which voting rights are effectively held;
- (c) the date on which control was acquired.

4. In its notification to the non-listed company, the AIFM shall request the board of directors of the company to inform the employees' representatives or, where there are none, the employees themselves, without undue delay of the acquisition of control by the AIF managed by the AIFM and of the information referred to in paragraph 3. The AIFM shall use its best efforts to ensure that the employees' representatives or, where there are none, the employees themselves, are duly informed by the board of directors in accordance with this Article.

5. The notifications referred to in paragraphs 1, 2 and 3 shall be made as soon as possible, but no later than 10 working days after the date on which the AIF has reached, exceeded or fallen below the relevant threshold or has acquired control over the non-listed company.

Article 28

Disclosure in case of acquisition of control

1. Member States shall require that when an AIF acquires, individually or jointly, control of a non-listed company or an issuer pursuant to Article 26(1), in conjunction with paragraph 5 of that Article, the AIFM managing such AIF shall make the information referred to in paragraph 2 of this Article available to:

- (a) the company concerned;
- (b) the shareholders of the company of which the identities and addresses are available to the AIFM or can be made available by the company or through a register to which the AIFM has or can obtain access; and
- (c) the competent authorities of the home Member State of the AIFM.

Member States may require that the information referred to in paragraph 2 is also made available to the competent authorities of the non-listed company which the Member States may designate to that effect.

2. The AIFM shall make available:

- (a) the identity of the AIFMs which either individually or in agreement with other AIFMs manage the AIFs that have acquired control;
- (b) the policy for preventing and managing conflicts of interest, in particular between the AIFM, the AIF and the company, including information about the specific safeguards established to ensure that any agreement between the AIFM and/or the AIF and the company is concluded at arm's length; and
- (c) the policy for external and internal communication relating to the company in particular as regards employees.

3. In its notification to the company pursuant to point (a) of paragraph 1, the AIFM shall request the board of directors of the company to inform the employees' representatives or, where there are none, the employees themselves, without undue delay of the information referred to in paragraph 1. The AIFM shall use its best efforts to ensure that the employees' representatives or, where there are none, the employees themselves, are duly informed by the board of directors in accordance with this Article.

4. Member States shall require that when an AIF acquires, individually or jointly, control of a non-listed company pursuant to Article 26(1), in conjunction with paragraph 5 of that Article, the AIFM managing such AIF ensure that the AIF, or the AIFM acting on behalf of the AIF, disclose its intentions with regard to the future business of the non-listed company and the likely repercussions on employment, including any material change in the conditions of employment, to:

- (a) the non-listed company; and
- (b) the shareholders of the non-listed company of which the identities and addresses are available to the AIFM or can be made available by the non-listed company or through a register to which the AIFM has or can obtain access.

In addition, the AIFM managing the relevant AIF shall request and use its best efforts to ensure that the board of directors of the non-listed company makes available the information set out in the first subparagraph to the employees' representatives or, where there are none, the employees themselves, of the non-listed company.

5. Member States shall require that when an AIF acquires control of a non-listed company pursuant to Article 26(1), in conjunction with paragraph 5 of that Article, the AIFM managing such an AIF provide the competent authorities of its home Member State and the AIF's investors with information on the financing of the acquisition.

Article 29

Specific provisions regarding the annual report of AIFs exercising control of non-listed companies

1. Member States shall require that when an AIF acquires, individually or jointly, control of a non-listed company pursuant to Article 26(1), in conjunction with paragraph 5 of that Article, the AIFM managing such an AIF shall either:

- (a) request and use its best efforts to ensure that the annual report of the non-listed company drawn up in accordance with paragraph 2 is made available by the board of directors of the company to the employees' representatives or, where there are none, to the employees themselves within the period such annual report has to be drawn up in accordance with the national applicable law; or
- (b) for each such AIF include in the annual report provided for in Article 22 the information referred to in paragraph 2 relating to the relevant non-listed company.

2. The additional information to be included in the annual report of the company or the AIF, in accordance with paragraph 1, shall include at least a fair review of the development of the

company's business representing the situation at the end of the period covered by the annual report. The report shall also give an indication of:

- (a) any important events that have occurred since the end of the financial year;
- (b) the company's likely future development; and
- (c) the information concerning acquisitions of own shares prescribed by Article 22(2) of Council Directive 77/91/EEC⁽¹⁾.

3. The AIFM managing the relevant AIF shall either:

- (a) request and use its best efforts to ensure that the board of directors of the non-listed company makes available the information referred to in point (b) of paragraph 1 relating to the company concerned to the employees' representatives of the company concerned or, where there are none, to the employees themselves within the period referred to in Article 22(1); or
- (b) make available the information referred to in point (a) of paragraph 1 to the investors of the AIF, in so far as already available, within the period referred to in Article 22(1) and, in any event, no later than the date on which the annual report of the non-listed company is drawn up in accordance with the national applicable law.

Article 30

Asset stripping

1. Member States shall require that when an AIF, individually or jointly, acquires control of a non-listed company or an issuer pursuant to Article 26(1), in conjunction with paragraph 5 of that Article, the AIFM managing such an AIF shall for a period of 24 months following the acquisition of control of the company by the AIF:

- (a) not be allowed to facilitate, support or instruct any distribution, capital reduction, share redemption and/or acquisition of own shares by the company as described in paragraph 2;
- (b) in so far as the AIFM is authorised to vote on behalf of the AIF at the meetings of the governing bodies of the company, not vote in favour of a distribution, capital reduction, share redemption and/or acquisition of own shares by the company as described in paragraph 2; and
- (c) in any event use its best efforts to prevent distributions, capital reductions, share redemptions and/or the acquisition of own shares by the company as described in paragraph 2.

⁽¹⁾ OJ L 26, 31.1.1977, p. 1.

2. The obligations imposed on AIFMs pursuant to paragraph 1 shall relate to the following:

- (a) any distribution to shareholders made when on the closing date of the last financial year the net assets as set out in the company's annual accounts are, or following such a distribution would become, lower than the amount of the subscribed capital plus those reserves which may be not distributed under the law or the statutes, on the understanding that where the uncalled part of the subscribed capital is not included in the assets shown in the balance sheet, this amount shall be deducted from the amount of subscribed capital;
- (b) any distribution to shareholders the amount of which would exceed the amount of the profits at the end of the last financial year plus any profits brought forward and sums drawn from reserves available for this purpose, less any losses brought forward and sums placed to reserve in accordance with the law or the statutes;
- (c) to the extent that acquisitions of own shares are permitted, the acquisitions by the company, including shares previously acquired by the company and held by it, and shares acquired by a person acting in his own name but on the company's behalf, that would have the effect of reducing the net assets below the amount mentioned in point (a).

3. For the purposes of paragraph 2:

- (a) the term 'distribution' referred to in points (a) and (b) of paragraph 2 shall include, in particular, the payment of dividends and of interest relating to shares;
- (b) the provisions on capital reductions shall not apply on a reduction in the subscribed capital, the purpose of which is to offset losses incurred or to include sums of money in a non-distributable reserve provided that, following that operation, the amount of such reserve is not more than 10 % of the reduced subscribed capital; and
- (c) the restriction set out in point (c) of paragraph 2 shall be subject to points (b) to (h) of Article 20(1) of Directive 77/91/EEC.

CHAPTER VI

RIGHTS OF EU AIFMs TO MARKET AND MANAGE EU AIFs IN THE UNION

Article 31

Marketing of units or shares of EU AIFs in the home Member State of the AIFM

1. Member States shall ensure that an authorised EU AIFM may market units or shares of any EU AIF that it manages to professional investors in the home Member State of the AIFM as soon as the conditions laid down in this Article are met.

Where the EU AIF is a feeder AIF the right to market referred to in the first subparagraph is subject to the condition that the master AIF is also an EU AIF which is managed by an authorised EU AIFM.

2. The AIFM shall submit a notification to the competent authorities of its home Member State in respect of each EU AIF that it intends to market.

That notification shall comprise the documentation and information set out in Annex III.

3. Within 20 working days following receipt of a complete notification file pursuant to paragraph 2, the competent authorities of the home Member State of the AIFM shall inform the AIFM whether it may start marketing the AIF identified in the notification referred to in paragraph 2. The competent authorities of the home Member State of the AIFM shall prevent the marketing of the AIF only if the AIFM's management of the AIF does not or will not comply with this Directive or the AIFM otherwise does not or will not comply with this Directive. In the case of a positive decision, the AIFM may start marketing the AIF in its home Member State from the date of the notification by the competent authorities to that effect.

In so far as they are different, the competent authorities of the home Member State of the AIFM shall also inform the competent authorities of the AIF that the AIFM may start marketing units or shares of the AIF.

4. In the event of a material change to any of the particulars communicated in accordance with paragraph 2, the AIFM shall give written notice of that change to the competent authorities of its home Member State at least 1 month before implementing the change as regards any changes planned by the AIFM, or immediately after an unplanned change has occurred.

If, pursuant to a planned change, the AIFM's management of the AIF would no longer comply with this Directive or the AIFM would otherwise no longer comply with this Directive, the relevant competent authorities shall inform the AIFM without undue delay that it is not to implement the change.

If a planned change is implemented notwithstanding the first and second subparagraphs or if an unplanned change has taken place pursuant to which the AIFM's management of the AIF no longer complies with this Directive or the AIFM otherwise no longer complies with this Directive, the competent authorities of the home Member State of the AIFM shall take all due measures in accordance with Article 46, including, if necessary, the express prohibition of marketing of the AIF.

5. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to determine:

- (a) the form and content of a model for the notification letter referred to in paragraph 2; and
- (b) the form of the written notice referred to in paragraph 4.

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 1095/2010.

6. Without prejudice to Article 43(1), Member States shall require that AIFs managed and marketed by AIFMs be marketed only to professional investors.

Article 32

Marketing of units or shares of EU AIFs in Member States other than in the home Member State of the AIFM

1. Member States shall ensure that an authorised EU AIFM may market units or shares of an EU AIF that it manages to professional investors in another Member State than the home Member State of the AIFM as soon as the conditions laid down in this Article are met.

Where the EU AIF is a feeder AIF the right to market referred to in the first subparagraph is subject to the condition that the master AIF is also an EU AIF and is managed by an authorised EU AIFM.

2. The AIFM shall submit a notification to the competent authorities of its home Member State in respect of each EU AIF that it intends to market.

That notification shall comprise the documentation and information set out in Annex IV.

3. The competent authorities of the home Member State of the AIFM shall, no later than 20 working days after the date of receipt of the complete notification file referred to in paragraph 2, transmit the complete notification file to the competent authorities of the Member States where it is intended that the AIF be marketed. Such transmission shall occur only if the AIFM's management of the AIF complies with and will continue to comply with this Directive and if the AIFM otherwise complies with this Directive.

The competent authorities of the home Member State of the AIFM shall enclose a statement to the effect that the AIFM concerned is authorised to manage AIFs with a particular investment strategy.

4. Upon transmission of the notification file, the competent authorities of the home Member State of the AIFM shall, without delay, notify the AIFM about the transmission. The AIFM may start marketing the AIF in the host Member State of the AIFM as of the date of that notification.

In so far as they are different, the competent authorities of the home Member State of the AIFM shall also inform the competent authorities of the AIF that the AIFM may start marketing the units or shares of the AIF in the host Member State of the AIFM.

5. Arrangements referred to in point (h) of Annex IV shall be subject to the laws and supervision of the host Member State of the AIFM.

6. Member States shall ensure that the notification letter by the AIFM referred to in paragraph 2 and the statement referred to in paragraph 3 are provided in a language customary in the sphere of international finance.

Member States shall ensure that electronic transmission and filing of the documents referred to in paragraph 3 are accepted by their competent authorities.

7. In the event of a material change to any of the particulars communicated in accordance with paragraph 2, the AIFM shall give written notice of that change to the competent authorities of its home Member State at least 1 month before implementing a planned change, or immediately after an unplanned change has occurred.

If, pursuant to a planned change, the AIFM's management of the AIF would no longer comply with this Directive or the AIFM would otherwise no longer comply with this Directive, the relevant competent authorities shall inform the AIFM without undue delay that it is not to implement the change.

If a planned change is implemented notwithstanding the first and second subparagraphs or if an unplanned change has taken place pursuant to which the AIFM's management of the AIF would no longer comply with this Directive or the AIFM otherwise would no longer comply with this Directive, the competent authorities of the home Member State of the AIFM shall take all due measures in accordance with Article 46, including, if necessary, the express prohibition of marketing of the AIF.

If the changes are acceptable because they do not affect the compliance of the AIFM's management of the AIF with this Directive, or the compliance by the AIFM with this Directive otherwise, the competent authorities of the home Member State of the AIFM shall, without delay, inform the competent authorities of the host Member State of the AIFM of those changes.

8. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to determine:

- (a) the form and content of a model for the notification letter referred to in paragraph 2;

- (b) the form and content of a model for the statement referred to in paragraph 3;
- (c) the form of the transmission referred to in paragraph 3; and
- (d) the form of the written notice referred to in paragraph 7.

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 1095/2010.

9. Without prejudice to Article 43(1), Member States shall require that the AIFs managed and marketed by the AIFM be marketed only to professional investors.

Article 33

Conditions for managing EU AIFs established in other Member States

1. Member States shall ensure that an authorised EU AIFM may manage EU AIFs established in another Member State either directly or by establishing a branch, provided that the AIFM is authorised to manage that type of AIF.

2. An AIFM intending to manage EU AIFs established in another Member State for the first time shall communicate the following information to the competent authorities of its home Member State:

- (a) the Member State in which it intends to manage AIFs directly or establish a branch;
- (b) a programme of operations stating in particular the services which it intends to perform and identifying the AIFs it intends to manage.

3. If the AIFM intends to establish a branch, it shall provide the following information in addition to that referred to in paragraph 2:

- (a) the organisational structure of the branch;
- (b) the address in the home Member State of the AIF from which documents may be obtained;
- (c) the names and contact details of the persons responsible for the management of the branch.

4. The competent authorities of the home Member State of the AIFM shall, within 1 month of receiving the complete documentation in accordance with paragraph 2 or within 2 months of receiving the complete documentation in accordance with paragraph 3, transmit the complete documentation to the competent authorities of the host Member State of the AIFM. Such transmission shall occur only if the AIFM's management of the AIF complies, and will continue to comply, with this Directive and the AIFM otherwise complies with this Directive.

The competent authorities of the home Member State of the AIFM shall enclose a statement to the effect that the AIFM concerned is authorised by them.

The competent authorities of the home Member State of the AIFM shall immediately notify the AIFM about the transmission.

Upon receipt of the transmission notification the AIFM may start to provide its services in its host Member State.

5. The host Member State of the AIFM shall not impose any additional requirements on the AIFM concerned in respect of the matters covered by this Directive.

6. In the event of a change to any of the information communicated in accordance with paragraph 2, and, where relevant, paragraph 3, an AIFM shall give written notice of that change to the competent authorities of its home Member State at least 1 month before implementing planned changes, or immediately after an unplanned change has occurred.

If, pursuant to a planned change, the AIFM's management of the AIF would no longer comply with this Directive or the AIFM would otherwise no longer comply with this Directive, the competent authorities of the home Member State of the AIFM shall inform the AIFM without undue delay that it is not to implement the change.

If a planned change is implemented notwithstanding the first and second subparagraphs or if an unplanned change has taken place pursuant to which the AIFM's management of the AIF would no longer comply with this Directive or the AIFM otherwise would no longer comply with this Directive, the competent authorities of the home Member State of the AIFM shall take all due measures in accordance with Article 46.

If the changes are acceptable because they do not affect the compliance of the AIFM's management of the AIF with this Directive, or the compliance by the AIFM with this Directive otherwise, the competent authorities of the home Member State of the AIFM shall, without undue delay, inform the competent authorities of the host Member States of the AIFM of those changes.

7. In order to ensure consistent harmonisation of this Article, ESMA may develop draft regulatory technical standards to specify the information to be notified in accordance with paragraphs 2 and 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 1095/2010.

8. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to establish standard forms, templates and procedures for the transmission of information in accordance with paragraphs 2 and 3.

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 1095/2010.

CHAPTER VII

SPECIFIC RULES IN RELATION TO THIRD COUNTRIES

Article 34

Conditions for EU AIFMs which manage non-EU AIFs which are not marketed in Member States

1. Member States shall ensure that an authorised EU AIFM may manage non-EU AIFs which are not marketed in the Union provided that:

- (a) the AIFM complies with all the requirements established in this Directive except for Article 21 and 22 in respect of those AIFs; and
- (b) appropriate cooperation arrangements are in place between the competent authorities of the home Member State of the AIFM and the supervisory authorities of the third country where the non-EU AIF is established in order to ensure at least an efficient exchange of information that allows competent authorities of the home Member State of the AIFM to carry out their duties in accordance with this Directive.

2. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures regarding the cooperation arrangements referred to in paragraph 1 in order to design a common framework to facilitate the establishment of those cooperation arrangements with third countries.

3. In order to ensure uniform application of this Article, ESMA shall develop guidelines to determine the conditions of application of the measures adopted by the Commission regarding the cooperation arrangements referred to in paragraph 1.

Article 35

Conditions for the marketing in the Union with a passport of a non-EU AIF managed by an EU AIFM

1. Member States shall ensure that an authorised EU AIFM may market to professional investors in the Union units or shares of non-EU AIFs it manages and of EU feeder AIFs that do not fulfil the requirements referred to in the second

subparagraph of Article 31(1) as soon as the conditions laid down in this Article are met.

2. AIFMs shall comply with all the requirements established in this Directive, with the exception of Chapter VI. In addition the following conditions shall be met:

- (a) appropriate cooperation arrangements must be in place between the competent authorities of the home Member State of the AIFM and the supervisory authorities of the third country where the non-EU AIF is established in order to ensure at least an efficient exchange of information, taking into account Article 50(4), that allows the competent authorities to carry out their duties in accordance with this Directive;
- (b) the third country where the non-EU AIF is established is not listed as a Non-Cooperative Country and Territory by FATF;
- (c) the third country where the non-EU AIF is established has signed an agreement with the home Member State of the authorised AIFM and with each other Member State in which the units or shares of the non-EU AIF are intended to be marketed, which fully complies with the standards laid down in Article 26 of the OECD Model Tax Convention on Income and on Capital and ensures an effective exchange of information in tax matters, including any multilateral tax agreements.

Where a competent authority of another Member State disagrees with the assessment made on the application of points (a) and (b) of the first subparagraph by the competent authorities of the home Member State of the AIFM, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

3. If an AIFM intends to market units or shares of non-EU AIFs in its home Member State, the AIFM shall submit a notification to the competent authorities of its home Member State in respect of each non-EU AIF that it intends to market.

That notification shall comprise the documentation and information set out in Annex III.

4. No later than 20 working days after receipt of a complete notification pursuant to paragraph 3, the competent authorities of the home Member State of the AIFM shall inform the AIFM whether it may start marketing the AIF identified in the notification referred to in paragraph 3 in its territory. The competent authorities of the home Member State of the AIFM shall prevent the marketing of the AIF only if the AIFM's management of the AIF does not or will not comply with this Directive or the AIFM otherwise does not or will not comply with this Directive. In the case of a positive decision, the AIFM may start marketing the AIF in its home Member State as of the date of the notification by the competent authorities to that effect.

The competent authorities of the home Member State of the AIFM shall also inform ESMA that the AIFM may start marketing the units or shares of the AIF in the home Member State of the AIFM.

5. If an AIFM intends to market units or shares of non-EU AIFs in a Member State other than its home Member State, the AIFM shall submit a notification to the competent authorities of its home Member State in respect of each non-EU AIF that it intends to market.

That notification shall comprise the documentation and information set out in Annex IV.

6. The competent authorities of the home Member State of the AIFM shall, no later than 20 working days after the date of receipt of the complete notification file referred to in paragraph 5, transmit that complete notification file to the competent authorities of the Member State where the AIF is intended to be marketed. Such transmission will occur only if the AIFM's management of the AIF complies and will continue to comply with this Directive and that the AIFM otherwise complies with this Directive.

The competent authorities of the home Member State of the AIFM shall enclose a statement to the effect that the AIFM concerned is authorised to manage AIFs with a particular investment strategy.

7. Upon transmission of the notification file, the competent authorities of the home Member State of the AIFM shall, without delay, notify the AIFM about the transmission. The AIFM may start marketing the AIF in the relevant host Member States of the AIFM as of the date of that notification by the competent authorities.

The competent authorities of the home Member State of the AIFM shall also inform ESMA that the AIFM may start marketing the units or shares of the AIF in the host Member States of the AIFM.

8. Arrangements referred to in point (h) of Annex IV shall be subject to the laws and supervision of the host Member States of the AIFM.

9. Member States shall ensure that the notification letter of the AIFM referred to in paragraph 5 and the statement referred to in paragraph 6 are provided in a language customary in the sphere of international finance.

Member States shall ensure that electronic transmission and filing of the documents referred to in paragraph 6 are accepted by their competent authorities.

10. In the event of a material change to any of the particulars communicated in accordance with paragraph 3 or 5, the AIFM shall give written notice of that change to the competent authorities of its home Member State, at least 1

month before implementing a planned change, or immediately after an unplanned change has occurred.

If pursuant to a planned change, the AIFM's management of the AIF would no longer comply with this Directive or the AIFM would no longer comply with this Directive, the competent authorities of the home Member State of the AIFM shall inform the AIFM without undue delay that it is not to implement the change.

If a planned change is implemented notwithstanding the first and second subparagraphs, or if an unplanned change has taken place pursuant to which the AIFM's management of the AIF would no longer comply with this Directive or the AIFM otherwise would no longer comply with this Directive, the competent authorities of the home Member State of the AIFM shall take all due measures in accordance with Article 46, including, if necessary, the express prohibition of marketing of the AIF.

If the changes are acceptable because they do not affect the compliance of the AIFM's management of the AIF with this Directive, or the compliance by the AIFM with this Directive otherwise, the competent authorities of the home Member State of the AIFM shall, without delay, inform ESMA in so far as the changes concern the termination of the marketing of certain AIFs or additional AIFs marketed and, if applicable, the competent authorities of the host Member States of the AIFM of those changes.

11. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures regarding the cooperation arrangements referred to in point (a) of paragraph 2 in order to design a common framework to facilitate the establishment of those cooperation arrangements with third countries.

12. In order to ensure uniform application of this Article, ESMA may develop guidelines to determine the conditions of application of the measures adopted by the Commission regarding the cooperation arrangements referred to in point (a) of paragraph 2.

13. ESMA shall develop draft regulatory technical standards to determine the minimum content of the cooperation arrangements referred to in point (a) of paragraph 2 so as to ensure that both the competent authorities of the home and the host Member States receive sufficient information in order to be able to exercise their supervisory and investigatory powers under this Directive.

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

14. In order to ensure consistent harmonisation of this Article, ESMA shall develop draft regulatory technical standards to specify the procedures for coordination and exchange of information between the competent authority of the home Member State and the competent authorities of the host Member States of the AIFM.

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.

15. In case a competent authority rejects a request to exchange information in accordance with the regulatory technical standards referred to in paragraph 14, the competent authorities concerned may refer the matter to ESMA, which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

16. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to determine:

- (a) the form and content of a model for the notification letter referred to in paragraph 3;
- (b) the form and content of a model for the notification letter referred to in paragraph 5;
- (c) the form and content of a model for the statement referred to in paragraph 6;
- (d) the form of the transmission referred to in paragraph 6;
- (e) the form of the written notice referred to in paragraph 10.

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 1095/2010.

17. Without prejudice to Article 43(1), Member States shall require that the AIFs managed and marketed by the AIFM be marketed only to professional investors.

Article 36

Conditions for the marketing in Member States without a passport of non-EU AIFs managed by an EU AIFM

1. Without prejudice to Article 35, Member States may allow an authorised EU AIFM to market to professional investors, in their territory only, units or shares of non-EU AIFs it manages and of EU feeder AIFs that do not fulfil the requirements

referred to in the second subparagraph of Article 31(1), provided that:

- (a) the AIFM complies with all the requirements established in this Directive with the exception of Article 21. That AIFM shall however ensure that one or more entities are appointed to carry out the duties referred to in Article 21(7), (8) and (9). The AIFM shall not perform those functions. The AIFM shall provide its supervisory authorities with information about the identity of those entities responsible for carrying out the duties referred to in Article 21(7), (8) and (9);
- (b) appropriate cooperation arrangements for the purpose of systemic risk oversight and in line with international standards are in place between the competent authorities of the home Member State of the AIFM and the supervisory authorities of the third country where the non-EU AIF is established in order to ensure an efficient exchange of information that allows the competent authorities of the home Member State of the AIFM to carry out their duties in accordance with this Directive;
- (c) the third country where the non-EU AIF is established is not listed as a Non-Cooperative Country and Territory by FATF.

2. Member States may impose stricter rules on the AIFM in respect of the marketing of units or shares of non-EU AIFs to investors in their territory for the purpose of this Article.

3. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures regarding the cooperation arrangements referred to in paragraph 1 in order to design a common framework to facilitate the establishment of those cooperation arrangements with third countries.

4. In order to ensure uniform application of this Article, ESMA shall develop guidelines to determine the conditions of application of the measures adopted by the Commission regarding the cooperation arrangements referred to in paragraph 1.

Article 37

Authorisation of non-EU AIFMs intending to manage EU AIFs and/or market AIFs managed by them in the Union in accordance with Article 39 or 40

1. Member States shall require that non-EU AIFMs intending to manage EU AIFs and/or to market AIFs managed by them in the Union in accordance with Article 39 or 40 acquire prior authorisation by the competent authorities of their Member State of reference in accordance with this Article.

2. A non-EU AIFM intending to obtain prior authorisation as referred to in paragraph 1 shall comply with this Directive, with the exception of Chapter VI. If and to the extent that compliance with a provision of this Directive is incompatible with compliance with the law to which the non-EU AIFM and/or the non-EU AIF marketed in the Union is subject, there shall be no obligation on the AIFM to comply with that provision of this Directive if it can demonstrate that:

- (a) it is impossible to combine such compliance with compliance with a mandatory provision in the law to which the non-EU AIFM and/or the non-EU AIF marketed in the Union is subject;
- (b) the law to which the non-EU AIFM and/or the non-EU AIF is subject provides for an equivalent rule having the same regulatory purpose and offering the same level of protection to the investors of the relevant AIF; and
- (c) the non-EU AIFM and/or the non-EU AIF complies with the equivalent rule referred to in point (b).

3. A non-EU AIFM intending to obtain prior authorisation as referred to in paragraph 1 shall have a legal representative established in its Member State of reference. The legal representative shall be the contact point of the AIFM in the Union and any official correspondence between the competent authorities and the AIFM and between the EU investors of the relevant AIF and the AIFM as set out in this Directive shall take place through that legal representative. The legal representative shall perform the compliance function relating to the management and marketing activities performed by the AIFM under this Directive together with the AIFM.

4. The Member State of reference of a non-EU AIFM shall be determined as follows:

- (a) if the non-EU AIFM intends to manage only one EU AIF, or several EU AIFs established in the same Member State, and does not intend to market any AIF in accordance with Article 39 or 40 in the Union, the home Member State of that or those AIFs is deemed to be the Member State of reference and the competent authorities of this Member State will be competent for the authorisation procedure and for the supervision of the AIFM;
- (b) if the non-EU AIFM intends to manage several EU AIFs established in different Member States and does not intend to market any AIF in accordance with Article 39 or 40 in the Union, the Member State of reference is either:
 - (i) the Member State where most of the AIFs are established; or
 - (ii) the Member State where the largest amount of assets is being managed;
- (c) if the non-EU AIFM intends to market only one EU AIF in only one Member State, the Member State of reference is determined as follows:
 - (i) if the AIF is authorised or registered in a Member State, the home Member State of the AIF or the Member State where the AIFM intends to market the AIF;
 - (ii) if the AIF is not authorised or registered in a Member State, the Member State where the AIFM intends to market the AIF;
- (d) if the non-EU AIFM intends to market only one non-EU AIF in only one Member State, the Member State of reference is that Member State;
- (e) if the non-EU AIFM intends to market only one EU AIF, but in different Member States, the Member State of reference is determined as follows:
 - (i) if the AIF is authorised or registered in a Member State, the home Member State of the AIF or one of the Member States where the AIFM intends to develop effective marketing; or
 - (ii) if the AIF is not authorised or registered in a Member State, one of the Member States where the AIFM intends to develop effective marketing;
- (f) if the non-EU AIFM intends to market only one non-EU AIF, but in different Member States, the Member State of reference is one of those Member States;
- (g) if the non-EU AIFM intends to market several EU AIFs in the Union, the Member State of reference is determined as follows:
 - (i) in so far as those AIFs are all registered or authorised in the same Member State, the home Member State of those AIFs or the Member State where the AIFM intends to develop effective marketing for most of those AIFs;

- (ii) in so far as those AIFs are not all registered or authorised in the same Member State, the Member State where the AIFM intends to develop effective marketing for most of those AIFs;
- (h) if the non-EU AIFM intends to market several EU and non-EU AIFs, or several non-EU AIFs in the Union, the Member State of reference is the Member State where it intends to develop effective marketing for most of those AIFs.

In accordance with the criteria set out in points (b), (c)(i), (e), (f), and (g)(i) of the first subparagraph, more than one Member State of reference is possible. In such cases, Member States shall require that the non-EU AIFM intending to manage EU AIFs without marketing them and/or market AIFs managed by it in the Union in accordance with Article 39 or 40 submit a request to the competent authorities of all of the Member States that are possible Member States of reference in accordance with the criteria set out in those points, to determine its Member State of reference from among them. Those competent authorities shall jointly decide the Member State of reference for the non-EU AIFM, within 1 month of receipt of such request. The competent authorities of the Member State that is appointed as Member State of reference shall, without undue delay, inform the non-EU AIFM of that appointment. If the non-EU AIFM is not duly informed of the decision made by the relevant competent authorities within 7 days of the decision or if the relevant competent authorities have not made a decision within the 1-month period, the non-EU AIFM may itself choose its Member State of reference based on the criteria set out in this paragraph.

The AIFM shall be able to prove its intention to develop effective marketing in a particular Member State by disclosure of its marketing strategy to the competent authorities of the Member State indicated by it.

5. Member States shall require that a non-EU AIFM intending to manage EU AIFs without marketing them and/or to market AIFs managed by it in the Union in accordance with Article 39 or 40 submit a request for authorisation to its Member State of reference.

After receiving the application for authorisation, the competent authorities shall assess whether the determination by the AIFM as regards its Member State of reference complies with the criteria laid down in paragraph 4. If the competent authorities consider that this is not the case, they shall refuse the authorisation request of the non-EU AIFM explaining the reasons for their refusal. If the competent authorities consider that the criteria of paragraph 4 have been complied with, they shall notify ESMA, requesting advice on their assessment. In their notification to ESMA, the competent authorities shall provide ESMA with the justification by the AIFM of its assessment

regarding the Member State of reference and with information on the marketing strategy of the AIFM.

Within 1 month of having received the notification referred to in the second subparagraph, ESMA shall issue advice to the relevant competent authorities about their assessment on the Member State of reference in accordance with the criteria set out in paragraph 4. ESMA shall issue a negative advice only if it considers that the criteria set out in paragraph 4 have not been complied with.

The term referred to in Article 8(5) shall be suspended during ESMA's deliberation in accordance with this paragraph.

If the competent authorities propose to grant authorisation contrary to ESMA's advice referred to in the third subparagraph they shall inform ESMA, stating their reasons. ESMA shall publish the fact that the competent authorities do not comply or intend to comply with its advice. ESMA may also decide, on a case-by-case basis, to publish the reasons provided by the competent authorities for not complying with that advice. The competent authorities shall receive advance notice about such a publication.

If the competent authorities propose to grant authorisation contrary to ESMA's advice referred to in the third subparagraph and the AIFM intends to market units or shares of AIFs managed by it in Member States other than the Member State of reference, the competent authorities of the Member State of reference shall also inform the competent authorities of those Member States thereof, stating their reasons. In so far as applicable, the competent authorities of the Member State of reference shall also inform the competent authorities of the home Member States of the AIFs managed by the AIFM thereof, stating their reasons.

6. Where a competent authority of a Member State disagrees with the determination of the Member State of reference by the AIFM, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

7. Without prejudice to paragraph 8, no authorisation shall be granted unless the following additional conditions are met:

- (a) the Member State of reference is indicated by the AIFM in accordance with the criteria set out in paragraph 4 and supported by the disclosure of the marketing strategy, and the procedure set out in paragraph 5 has been followed by the relevant competent authorities;
- (b) the AIFM has appointed a legal representative established in the Member State of reference;

- (c) the legal representative shall, together with the AIFM, be the contact person of the non-EU AIFM for the investors of the relevant AIFs, for ESMA and for the competent authorities as regards the activities for which the AIFM is authorised in the Union and shall at least be sufficiently equipped to perform the compliance function pursuant to this Directive;
- (d) appropriate cooperation arrangements are in place between the competent authorities of the Member State of reference, the competent authorities of the home Member State of the EU AIFs concerned and the supervisory authorities of the third country where the non-EU AIFM is established in order to ensure at least an efficient exchange of information that allows the competent authorities to carry out their duties in accordance with this Directive;
- (e) the third country where the non-EU AIFM is established is not listed as a Non-Cooperative Country and Territory by FATF;
- (f) the third country where the non-EU AIFM is established has signed an agreement with the Member State of reference, which fully complies with the standards laid down in Article 26 of the OECD Model Tax Convention on Income and on Capital and ensures an effective exchange of information in tax matters, including any multilateral tax agreements;
- (g) the effective exercise by the competent authorities of their supervisory functions under this Directive is neither prevented by the laws, regulations or administrative provisions of a third country governing the AIFM, nor by limitations in the supervisory and investigatory powers of that third country's supervisory authorities.

Where a competent authority of another Member State disagrees with the assessment made on the application of points (a) to (e) and (g) of this paragraph by the competent authorities of the Member State of reference of the AIFM, the competent authorities concerned may refer the matter to the ESMA, which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

Where a competent authority of an EU AIF does not enter into the required cooperation arrangements as set out in point (d) of the first subparagraph within a reasonable period of time, the competent authorities of the Member State of reference may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

8. The authorisation shall be given in accordance with Chapter II which shall apply *mutatis mutandis* subject to the following criteria:

- (a) the information referred to in Article 7(2) shall be supplemented by:
 - (i) a justification by the AIFM of its assessment regarding the Member State of reference in accordance with the criteria set out in paragraph 4 with information on the marketing strategy;
 - (ii) a list of the provisions of this Directive for which compliance by the AIFM is impossible as compliance by the AIFM with those provisions is, in accordance with paragraph 2, incompatible with compliance with a mandatory provision in the law to which the non-EU AIFM or the non-EU AIF marketed in the Union is subject;
 - (iii) written evidence based on the regulatory technical standards developed by ESMA that the relevant third country law provides for a rule equivalent to the provisions for which compliance is impossible, which has the same regulatory purpose and offers the same level of protection to the investors of the relevant AIFs and that the AIFM complies with that equivalent rule; such written evidence being supported by a legal opinion on the existence of the relevant incompatible mandatory provision in the law of the third country and including a description of the regulatory purpose and the nature of the investor protection pursued by it; and
 - (iv) the name of the legal representative of the AIFM and the place where it is established;
- (b) the information referred to in Article 7(3) may be limited to the EU AIFs the AIFM intends to manage and to those AIFs managed by the AIFM that it intends to market in the Union with a passport;
- (c) point (a) of Article 8(1) shall be without prejudice to paragraph 2 of this Article;
- (d) point (e) of Article 8(1) shall not apply;
- (e) the second subparagraph of Article 8(5) shall be read as including a reference to 'the information referred to in point (a) of Article 37(8)'.

Where a competent authority of another Member State disagrees with the authorisation granted by the competent authorities of the Member State of reference of the AIFM, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

9. In case the competent authorities of the Member State of reference consider that the AIFM may rely on paragraph 2 to be exempted from compliance with certain provisions of this Directive, they shall, without undue delay, notify ESMA thereof. They shall support this assessment by the information provided by the AIFM in accordance with points (a)(ii) and (iii) of paragraph 8.

Within 1 month of receipt of the notification referred to in the first subparagraph, ESMA shall issue advice to the competent authorities about the application of the exemption for compliance with this Directive caused by the incompatibility in accordance with paragraph 2. The advice may, in particular, address whether the conditions for such exemption appear to be met based on the information provided by the AIFM in accordance with points (a)(ii) and (iii) of paragraph 8 and on the regulatory technical standards on equivalence. ESMA shall seek to build a common European supervisory culture and consistent supervisory practices and ensure consistent approaches among competent authorities in relation to the application of this paragraph.

The term referred to in Article 8(5) shall be suspended during the ESMA review in accordance with this paragraph.

If the competent authorities of the Member State of reference propose to grant authorisation contrary to ESMA's advice referred to in the second subparagraph they shall inform ESMA, stating their reasons. ESMA shall publish the fact that the competent authorities do not comply or intend to comply with that advice. ESMA may also decide, on a case-by-case basis, to publish the reasons provided by the competent authorities for not complying with that advice. The competent authorities concerned shall receive advance notice of such publication.

If the competent authorities propose to grant authorisation contrary to the ESMA advice referred to in the second subparagraph and the AIFM intends to market units or shares of AIFs managed by it in Member States other than the Member State of reference, the competent authorities of the Member State of reference shall also inform the competent authorities of those Member States thereof, stating their reasons.

Where a competent authority of another Member State disagrees with the assessment made on the application of this paragraph by the competent authorities of the Member State of reference of the AIFM, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

10. The competent authorities of the Member State of reference shall, without undue delay, inform ESMA of the outcome of the initial authorisation process, about any changes in the authorisation of the AIFM and any withdrawal of authorisation.

The competent authorities shall inform ESMA about the applications for authorisation that they have rejected, providing data about the AIFM having asked for authorisation and the reasons for the rejection. ESMA shall keep a central register of those data, which shall be at the disposal of competent authorities, on request. Competent authorities shall treat this information as confidential.

11. The determination of the Member State of reference shall not be affected by the further business development of the AIFM in the Union. However, where the AIFM changes its marketing strategy within 2 years of its initial authorisation, and that change would have affected the determination of the Member State of reference if the modified marketing strategy had been the initial marketing strategy, the AIFM shall notify the competent authorities of the original Member State of reference of the change before implementing it and indicate its Member State of reference in accordance with the criteria set out in paragraph 4 and based on the new strategy. The AIFM shall justify its assessment by disclosing its new marketing strategy to its original Member State of reference. At the same time the AIFM shall provide information on its legal representative, including its name and the place where it is established. The legal representative shall be established in the new Member State of reference.

The original Member State of reference shall assess whether the determination of the AIFM in accordance with the first subparagraph is correct and shall notify ESMA thereof. ESMA shall issue advice on the assessment made by the competent authorities. In their notification to ESMA, the competent authorities shall provide the AIFM's justification of its assessment regarding the Member State of reference and information on the AIFM's new marketing strategy.

Within 1 month of receipt of the notification referred to in the second subparagraph, ESMA shall issue advice to the relevant competent authorities about their assessment. ESMA shall issue a negative advice only where it considers that the criteria set out in paragraph 4 have not been complied with.

After receipt of ESMA's advice in accordance with the third subparagraph, the competent authorities of the original Member State of reference shall inform the non-EU AIFM, its original legal representative and ESMA of their decision.

Where the competent authorities of the original Member State of reference agree with the assessment made by the AIFM, they shall also inform the competent authorities of the new Member State of reference of the change. The original Member State of reference shall, without undue delay, transfer a copy of the authorisation and the supervision file relating to the AIFM to the new Member State of reference. From the date of transmission of the authorisation and supervision file, the competent authorities of the new Member State of reference shall be competent for authorising and supervising the AIFM.

Where the competent authorities' final assessment is contrary to ESMA's advice referred to in the third subparagraph:

(a) the competent authorities shall inform ESMA thereof, stating reasons. ESMA shall publish the fact that the competent authorities do not comply, or intend not to comply, with its advice. ESMA may also decide, on a case-by-case basis, to publish the reasons for non-compliance provided by the competent authorities. The competent authorities concerned shall receive advance notice of such publication;

(b) where the AIFM markets units or shares of AIFs managed by it in Member States other than the original Member State of reference, the competent authorities of the original Member State of reference shall inform the competent authorities of those other Member States thereof, stating reasons. Where applicable, the competent authorities of the Member State of reference shall also inform the competent authorities of the home Member States of the AIFs managed by the AIFM thereof, stating reasons.

12. Where it appears from the actual course of the business development of the AIFM in the Union within 2 years after its authorisation that the marketing strategy as presented by the AIFM at the time of its authorisation was not followed, the AIFM made false statements in relation thereto or the AIFM has failed to comply with paragraph 11 when changing its marketing strategy, the competent authorities of the original Member State of reference shall request that the AIFM indicate the Member State of reference based on its actual marketing strategy. The procedure set out in paragraph 11 shall apply *mutatis mutandis*. If the AIFM does not comply with the competent authorities' request, they shall withdraw its authorisation.

Where the AIFM changes its marketing strategy after the period referred to in paragraph 11 and intends to change its Member State of reference on the basis of its new marketing strategy, it may submit a request to change its Member State of reference to the competent authorities of the original Member State of reference. The procedure referred to in paragraph 11 shall apply *mutatis mutandis*.

Where a competent authority of a Member State disagrees with the assessment made on the determination of the Member State of reference under paragraph 11 or under this paragraph, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

13. Any disputes arising between the competent authorities of the Member State of reference of the AIFM and the AIFM shall be settled in accordance with the law of and subject to the jurisdiction of the Member State of reference.

Any disputes between the AIFM or the AIF and EU investors of the relevant AIF shall be settled in accordance with the law of and subject to the jurisdiction of a Member State.

14. The Commission shall adopt implementing acts with a view to specifying the procedure to be followed by the possible Member States of reference when determining the Member State of reference from among those Member States in accordance with the second subparagraph of paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 59(2).

15. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures regarding the cooperation arrangements referred to in point (d) of paragraph 7 in order to design a common framework to facilitate the establishment of those cooperation arrangements with third countries.

16. In order to ensure uniform application of this Article, ESMA may develop guidelines to determine the conditions of application of the measures adopted by the Commission regarding the cooperation arrangements referred to in point (d) of paragraph 7.

17. ESMA shall develop draft regulatory technical standards to determine the minimum content of the cooperation arrangements referred to in point (d) of paragraph 7 so as to ensure that the competent authorities of the Member State of reference and the competent authorities of the host Member States receive sufficient information in order to be able to exercise their supervisory and investigatory powers under this Directive.

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.

18. In order to ensure consistent harmonisation of this Article, ESMA shall develop draft regulatory technical standards to specify the procedures for coordination and exchange of information between the competent authority of the Member State of reference and the competent authorities of the host Member States of the AIFM.

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.

19. In case a competent authority rejects a request to exchange information in accordance with the regulatory technical standards referred to in paragraph 17, the competent authorities concerned may refer the matter to ESMA, which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

20. In accordance with Article 29 of Regulation (EU) No 1095/2010, ESMA shall promote an effective bilateral and multilateral exchange of information between the competent authorities of the Member State of reference of the non-EU AIFM and the competent authorities of the host Member States of the AIFM concerned, with full respect for the applicable confidentiality and data protection provisions provided for in the relevant Union legislation.

21. In accordance with Article 31 of Regulation (EU) No 1095/2010, ESMA shall fulfil a general coordination role between the competent authority of the Member State of reference of the non-EU AIFM and the competent authorities of the host Member States of the AIFM concerned. In particular, ESMA may:

- (a) facilitate the exchange of information between the competent authorities concerned;
- (b) determine the scope of the information that the competent authority of the Member State of reference must provide to the competent authorities of the host Member States concerned;
- (c) take all appropriate measures in case of developments which may jeopardise the functioning of the financial markets with a view to facilitating the coordination of actions undertaken by the competent authority of the Member State of reference and the competent authorities of the host Member States in relation to non-EU AIFMs.

22. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to determine the form and content of the request referred to in the second subparagraph of paragraph 12.

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 1095/2010.

23. In order to ensure the uniform application of this Article, ESMA shall develop draft regulatory technical standards on the following:

- (a) the manner in which an AIFM must comply with the requirements laid down in this Directive, taking into account that the AIFM is established in a third country and, in particular, the presentation of the information required in Articles 22 to 24;
- (b) the conditions under which the law to which a non-EU AIFM or a non-EU AIF is subject is considered to provide for an equivalent rule having the same regulatory purpose and offering the same level of protection to the relevant investors.

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

Article 38

Peer review of authorisation and supervision of non-EU AIFMs

1. ESMA shall, on an annual basis, conduct a peer review analysis of the supervisory activities of the competent authorities in relation to the authorisation and the supervision of non-EU AIFMs under Articles 37, 39, 40 and 41, to further enhance consistency in supervisory outcomes, in accordance with Article 30 of Regulation (EU) No 1095/2010.

2. By 22 July 2013, ESMA shall develop methods to allow for objective assessment and comparison between the authorities reviewed.

3. In particular, the peer review analysis shall include an assessment of:

- (a) the degree of convergence in supervisory practices achieved in the authorisation and supervision of non-EU AIFMs;
- (b) the extent to which the supervisory practice achieves the objectives set out in this Directive;
- (c) the effectiveness and the degree of convergence achieved with regard to the enforcement of this Directive and its implementing measures and the regulatory and implementing technical standards developed by ESMA pursuant to this Directive, including administrative measures and penalties imposed against non-EU AIFMs where this Directive has not been complied with.

4. On the basis of the conclusions of the peer review, ESMA may issue guidelines and recommendations pursuant to Article 16 of Regulation (EU) No 1095/2010, with a view to establishing consistent, efficient and effective supervisory practices of non-EU AIFMs.

5. The competent authorities shall make every effort to comply with those guidelines and recommendations.

6. Within 2 months of the issuance of a guideline or recommendation, each competent authority shall confirm whether it complies or intends to comply with that guideline or recommendation. In the event that a competent authority does not comply or intend to comply, it shall inform ESMA, stating its reasons.

7. ESMA shall publish the fact that a competent authority does not comply or intend to comply with that guideline or recommendation. ESMA may also decide, on a case-by-case basis, to publish the reasons provided by the competent authority for not complying with that guideline or recommendation. The competent authority shall receive advance notice of such a publication.

8. In the report referred to in Article 43(5) of Regulation (EU) No 1095/2010, ESMA shall inform the European Parliament, the Council and the Commission of the guidelines and recommendations issued pursuant to this Article, stating which competent authorities have not complied with them, and outlining how ESMA intends to ensure that those competent authorities comply with its recommendations and guidelines in the future.

9. The Commission shall duly take those reports into account in its review of this Directive in accordance with Article 69 and in any subsequent evaluation that it conducts.

10. ESMA shall make the best practices that can be identified from peer reviews publicly available. In addition, all other results of peer reviews may be made public, subject to the agreement of the competent authority being the subject of the peer review.

Article 39

Conditions for the marketing in the Union with a passport of EU AIFs managed by a non-EU AIFM

1. Member States shall ensure that a duly authorised non-EU AIFM may market the units or shares of an EU AIF it manages to professional investors in the Union with a passport as soon as the conditions laid down in this Article are met.

2. In case the AIFM intends to market units or shares of the EU AIF in its Member State of reference, the AIFM shall submit a notification to the competent authorities of its Member State of reference in respect of each EU AIF that it intends to market.

That notification shall comprise the documentation and information set out in Annex III.

3. No later than 20 working days after receipt of a complete notification pursuant to paragraph 2, the competent authorities of the Member State of reference of the AIFM shall inform the AIFM whether it may start marketing the AIF identified in the notification referred to in paragraph 2 in its territory. The competent authorities of the Member State of reference of the AIFM may prevent the marketing of the AIF only if the AIFM's management of the AIF does not or will not comply with this Directive or if the AIFM otherwise does not or will not comply with this Directive. In the case of a positive decision, the AIFM may start marketing the AIF in its Member State of reference as of the date of the notification by the competent authorities to that effect.

The competent authorities of the Member State of reference of the AIFM shall also inform ESMA and the competent authorities of the AIF that the AIFM may start marketing units or shares of the AIF in the Member State of reference of the AIFM.

4. In case the AIFM intends to market units or shares of the EU AIF in Member States other than its Member State of reference, the AIFM shall submit a notification to the competent authorities of its Member State of reference in respect of each EU AIF that it intends to market.

That notification shall comprise the documentation and information set out in Annex IV.

5. The competent authorities of the Member State of reference shall, no later than 20 working days after the date of receipt of the complete notification file referred to in paragraph 4, transmit the complete notification file to the competent authorities of the Member States where the units or shares of the AIF are intended to be marketed. Such transmission shall be effected only if the AIFM's management of the AIF complies and will continue to comply with this Directive and if the AIFM otherwise complies with this Directive.

The competent authorities of the Member State of reference of the AIFM shall enclose a statement to the effect that the AIFM concerned is authorised to manage AIFs with a particular investment strategy.

6. Upon transmission of the notification file, the competent authorities of the Member State of reference of the AIFM shall, without delay, notify the AIFM about the transmission. The AIFM may start marketing the AIF in the relevant host Member States as of the date of that notification.

The competent authorities of the Member State of reference of the AIFM shall also inform ESMA and the competent authorities of the AIF that the AIFM may start marketing the units or shares of the AIF in the host Member States of the AIFM.

7. The arrangements referred to in point (h) of Annex IV shall be subject to the laws and supervision of the host Member States of the AIFM.

8. Member States shall ensure that the notification letter by the AIFM referred to in paragraph 4 and the statement referred to in paragraph 5 are provided in a language customary in the sphere of international finance.

Member States shall ensure that electronic transmission and filing of the documents referred to in paragraph 6 are accepted by their competent authorities.

9. In the event of a material change to any of the particulars communicated in accordance with paragraph 2 and/or 4, the AIFM shall give written notice of that change to the competent authorities of its Member State of reference at least 1 month before implementing a planned change, or immediately after an unplanned change has occurred.

If, pursuant to a planned change, the AIFM's management of the AIF would no longer comply with this Directive or the AIFM would otherwise no longer comply with this Directive, the competent authorities of the Member State of reference of the AIFM shall inform the AIFM, without undue delay, that it is not to implement the change.

If a planned change is implemented notwithstanding the first and second subparagraphs or if an unplanned change has taken place pursuant to which the AIFM's management of the AIF no longer complies with this Directive or the AIFM otherwise no longer complies with this Directive, the competent authorities of the Member State reference of the AIFM shall take all due measures in accordance with Article 46, including, if necessary, the express prohibition of marketing of the AIF.

If the changes are acceptable because they do not affect compliance of the AIFM's management of the AIF with this Directive, or compliance by the AIFM with this Directive otherwise, the competent authorities of the Member State of reference shall, without delay, inform ESMA in so far as the changes concern the termination of the marketing of certain AIFs or additional AIFs being marketed and, in so far as applicable, the competent authorities of the host Member States of those changes.

10. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to determine:

- (a) the form and content of a model for the notification letter referred to in paragraphs 2 and 4;
- (b) the form and content of a model for the statement referred to in paragraph 5;
- (c) the form of the transmission referred to in paragraph 5; and
- (d) the form of the written notice referred to in paragraph 9.

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 1095/2010.

11. Without prejudice to Article 43(1), Member States shall require that the AIFs managed and marketed by the AIFM be marketed only to professional investors.

Article 40

Conditions for the marketing in the Union with a passport of non-EU AIFs managed by a non-EU AIFM

1. Member States shall ensure that a duly authorised non-EU AIFM may market units or shares of a non-EU AIF it manages to professional investors in the Union with a passport as soon as the conditions laid down in this Article are met.

2. In addition to the requirements in this Directive in relation to EU-AIFMs, for non-EU AIFMs the following conditions shall be met:

- (a) appropriate cooperation arrangements are in place between the competent authorities of the Member State of reference and the supervisory authority of the third country where the non-EU AIF is established in order to ensure at least an efficient exchange of information that allows the competent authorities to carry out their duties in accordance with this Directive;
- (b) the third country where the non-EU AIF is established is not listed as a Non-Cooperative Country and Territory by FATF;
- (c) the third country where the non-EU AIF is established has signed an agreement with the Member State of reference and with each other Member State in which the units or shares of the non-EU AIF are intended to be marketed which fully complies with the standards laid down in Article 26 of the OECD Model Tax Convention on Income and on Capital and ensures an effective exchange of information in tax matters including any multilateral tax agreements.

Where a competent authority of another Member State disagrees with the assessment made on the application of points (a) and (b) of the first subparagraph by the competent authorities of the Member State of reference of the AIFM, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

3. The AIFM shall submit a notification to the competent authorities of its Member State of reference in respect of each non-EU AIF that it intends to market in its Member State of reference.

That notification shall comprise the documentation and information set out in Annex III.

4. No later than 20 working days after receipt of a complete notification pursuant to paragraph 3, the competent authorities of the Member State of reference of the AIFM shall inform the AIFM whether it may start marketing the AIF identified in the notification referred to in paragraph 3 in its territory. The competent authorities of the Member State of reference of the AIFM may prevent the marketing of the AIF only if the AIFM's management of the AIF does not or will not comply with this Directive or the AIFM otherwise does not or will not comply with this Directive. In the case of a positive decision, the AIFM may start marketing the AIF in its Member State of reference from the date of the notification by the competent authorities to that effect.

The competent authorities of the Member State of reference of the AIFM shall also inform ESMA that the AIFM may start marketing units or shares of the AIF in the Member State of reference of the AIFM.

5. If the AIFM intends to market the units or shares of a non-EU AIF also in Member States other than its Member State of reference, the AIFM shall submit a notification to the competent authorities of its Member State of reference in respect of each non-EU AIF that it intends to market.

That notification shall comprise the documentation and information set out in Annex IV.

6. The competent authorities of the Member State of reference shall, no later than 20 working days after the date of receipt of the complete notification file referred to in paragraph 5, transmit the complete notification file to the competent authorities of the Member States where the units or shares of the AIF are intended to be marketed. Such transmission shall occur only if the AIFM's management of the AIF complies and will continue to comply with this Directive and that in general the AIFM complies with this Directive.

The competent authorities of the Member State of reference of the AIFM shall enclose a statement to the effect that the AIFM concerned is authorised to manage AIFs with a particular investment strategy.

7. Upon transmission of the notification file, the competent authorities of the Member State of reference of the AIFM shall, without delay, notify the AIFM of the transmission. The AIFM may start marketing the AIF in the relevant host Member States of the AIFM as of the date of that notification.

The competent authorities of the Member State of reference of the AIFM shall also inform ESMA that the AIFM may start marketing the units or shares of the AIF in the host Member States of the AIFM.

8. Arrangements referred to in point (h) of Annex IV shall be subject to the laws and supervision of the host Member States of the AIFM, in so far as those Member States are different than the Member State of reference.

9. Member States shall ensure that the notification letter by the AIFM referred to in paragraph 5 and the statement referred to in paragraph 6 are provided in a language customary in the sphere of international finance.

Member States shall ensure that electronic transmission and filing of the documents referred to in paragraph 6 are accepted by their competent authorities.

10. In the event of a material change to any of the particulars communicated in accordance with paragraph 3 or 5, the AIFM shall give written notice of that change to the competent authorities of the Member State of reference at

least 1 month before implementing a planned change, or immediately after an unplanned change has occurred.

If, pursuant to a planned change, the AIFM's management of the AIF would no longer comply with this Directive, or the AIFM would otherwise no longer comply with this Directive, the competent authorities of the Member State of reference of the AIFM shall inform the AIFM, without undue delay, that it is not to implement the change.

If the planned change is implemented notwithstanding the first and second subparagraphs, or if an unplanned change has taken place pursuant to which the AIFM's management of the AIF no longer complies with this Directive or the AIFM otherwise no longer complies with this Directive, the competent authorities of the Member State of reference of the AIFM shall take all due measures in accordance with Article 46, including, if necessary, the express prohibition of marketing of the AIF.

If the changes are acceptable because they do not affect the compliance of the AIFM's management of the AIF with this Directive or the compliance by the AIFM with this Directive otherwise, the competent authorities of the Member State of reference shall, without delay, inform ESMA in so far as the changes concern the termination of the marketing of certain AIFs or additional AIFs being marketed and, in so far as applicable, the competent authorities of the host Member States of the AIFM of those changes.

11. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures regarding the cooperation arrangements referred to in point (a) of paragraph 2 in order to design a common framework to facilitate the establishment of those cooperation arrangements with third countries.

12. In order to ensure uniform application of this Article, ESMA may develop guidelines to determine the conditions of application of the measures adopted by the Commission regarding the cooperation arrangements referred to in point (a) of paragraph 2.

13. ESMA shall develop draft regulatory technical standards to determine the minimum content of the cooperation arrangements referred to in point (a) of paragraph 2 so as to ensure that the competent authorities of the Member State of reference and the competent authorities of the host Member States receive sufficient information in order to be able to exercise their supervisory and investigatory powers under this Directive.

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.

14. In order to ensure consistent harmonisation of this Article, ESMA shall develop draft regulatory technical standards to specify the procedures for coordination and exchange of information between the competent authority of the Member State of reference and the competent authorities of the host Member States of the AIFM.

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.

15. In case a competent authority rejects a request to exchange information in accordance with the regulatory technical standards referred to in paragraph 14, the competent authorities concerned may refer the matter to ESMA, which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

16. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to determine:

- (a) the form and content of a model for the notification letter referred to in paragraphs 3 and 5;
- (b) the form and content of a model for the statement referred to in paragraph 6;
- (c) the form of the transmission referred to in paragraph 6; and
- (d) the form of the written notice referred to in paragraph 10.

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 1095/2010.

17. Without prejudice to Article 43(1), Member States shall require that the AIFs managed and marketed by the AIFM be marketed only to professional investors.

Article 41

Conditions for managing AIFs established in Member States other than the Member State of reference by non-EU AIFMs

1. Member States shall ensure that an authorised non-EU AIFM may manage EU AIFs established in a Member State other than its Member State of reference either directly or via the establishment of a branch, provided that the AIFM is authorised to manage that type of AIF.

2. Any non-EU AIFM intending to manage EU AIFs established in another Member State than its Member State of reference for the first time shall communicate the following information to the competent authorities of its Member State of reference:

- (a) the Member State in which it intends to manage AIFs directly or establish a branch;
- (b) a programme of operations stating in particular the services which it intends to perform and identifying the AIFs it intends to manage.

3. If the non-EU AIFM intends to establish a branch, it shall provide, in addition to the information requested in paragraph 2, the following information:

- (a) the organisational structure of the branch;
- (b) the address in the home Member State of the AIF from which documents may be obtained;
- (c) the names and contact details of persons responsible for the management of the branch.

4. The competent authorities of the Member State of reference shall, within 1 month of receiving the complete documentation in accordance with paragraph 2 or within 2 months of receiving the complete documentation in accordance with paragraph 3, transmit that documentation to the competent authorities of the host Member States of the AIFM. Such transmission shall occur only if the AIFM's management of the AIF complies and will continue to comply with this Directive and the AIFM otherwise complies with this Directive.

The competent authorities of the Member State of reference shall enclose a statement to the effect that the AIFM concerned is authorised by them.

The competent authorities of the Member State of reference shall immediately notify the AIFM about the transmission. Upon receipt of the transmission notification the AIFM may start to provide its services in the host Member States of the AIFM.

The competent authorities of the Member State of reference shall also inform ESMA that the AIFM may start managing the AIF in the host Member States of the AIFM.

5. The host Member States of the AIFM shall not impose any additional requirements on the AIFM concerned in respect of the matters covered by this Directive.

6. In the event of a change to any of the information communicated in accordance with paragraph 2 and, if relevant, paragraph 3, an AIFM shall give written notice of that change to the competent authorities of its Member State of reference at least 1 month before implementing a planned change, or immediately after an unplanned change has occurred.

If, pursuant to a planned change, the AIFM's management of the AIF would no longer comply with this Directive or the AIFM would otherwise no longer comply with this Directive, the competent authorities of the Member State of reference shall inform the AIFM without undue delay that it is not to implement the change.

If a planned change is implemented notwithstanding the first and second subparagraphs or if an unplanned change has taken place pursuant to which the AIFM's management of the AIF no longer complies with this Directive or the AIFM otherwise no longer complies with this Directive, the competent authorities of the Member State of reference shall take all due measures in accordance with Article 46, including, if necessary, the express prohibition of marketing of the AIF.

If the changes are acceptable because they do not affect the compliance of the AIFM's management of the AIF with this Directive or the compliance by the AIFM with this Directive otherwise, the competent authorities of the Member State of reference shall without undue delay inform the competent authorities of the host Member States of the AIFM of those changes.

7. In order to ensure consistent harmonisation of this Article, ESMA may develop draft regulatory technical standards to specify the information to be notified in accordance with paragraphs 2 and 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 1095/2010.

8. In order to ensure uniform conditions of application of this Article, ESMA may develop draft implementing technical standards to establish standard forms, templates and procedures for the transmission of information in accordance with paragraphs 2 and 3.

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 1095/2010.

Article 42

Conditions for the marketing in Member States without a passport of AIFs managed by a non-EU AIFM

1. Without prejudice to Articles 37, 39 and 40, Member States may allow non-EU AIFMs to market to professional investors, in their territory only, units or shares of AIFs they manage subject at least to the following conditions:

- (a) the non-EU AIFM complies with Articles 22, 23 and 24 in respect of each AIF marketed by it pursuant to this Article and with Articles 26 to 30 where an AIF marketed by it pursuant to this Article falls within the scope of Article 26(1). Competent authorities and AIF investors referred to in those Articles shall be deemed those of the Member States where the AIFs are marketed;
- (b) appropriate cooperation arrangements for the purpose of systemic risk oversight and in line with international standards are in place between the competent authorities of the Member States where the AIFs are marketed, in so far as applicable, the competent authorities of the EU AIFs concerned and the supervisory authorities of the third country where the non-EU AIFM is established and, in so far as applicable, the supervisory authorities of the third country where the non-EU AIF is established in order to ensure an efficient exchange of information that allows competent authorities of the relevant Member States to carry out their duties in accordance with this Directive;
- (c) the third country where the non-EU AIFM or the non-EU AIF is established is not listed as a Non-Cooperative Country and Territory by FATF.

Where a competent authority of an EU AIF does not enter into the required cooperation arrangements as set out in point (b) of the first subparagraph within a reasonable period of time, the competent authorities of the Member State where the AIF is intended to be marketed may refer the matter to ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

2. Member States may impose stricter rules on the non-EU AIFM in respect of the marketing of units or shares of AIFs to investors in their territory for the purpose of this Article.

3. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures regarding the cooperation arrangements referred to in paragraph 1 in order to design a common framework to facilitate the establishment of those cooperation arrangements with third countries.

4. In order to ensure uniform application of this Article, ESMA shall develop guidelines to determine the conditions of application of the measures adopted by the Commission regarding the cooperation arrangements referred to in paragraph 1.

CHAPTER VIII

MARKETING TO RETAIL INVESTORS

Article 43

Marketing of AIFs by AIFMs to retail investors

1. Without prejudice to other instruments of Union law, Member States may allow AIFMs to market to retail investors in their territory units or shares of AIFs they manage in accordance with this Directive, irrespective of whether such AIFs are marketed on a domestic or cross-border basis or whether they are EU or non-EU AIFs.

In such cases, Member States may impose stricter requirements on the AIFM or the AIF than the requirements applicable to the AIFs marketed to professional investors in their territory in accordance with this Directive. However, Member States shall not impose stricter or additional requirements on EU AIFs established in another Member State and marketed on a cross-border basis than on AIFs marketed domestically.

2. Member States that permit the marketing of AIFs to retail investors in their territory shall, by 22 July 2014, inform the Commission and ESMA of:

- (a) the types of AIF which AIFMs may market to retail investors in their territory;
- (b) any additional requirements that the Member State imposes for the marketing of AIFs to retail investors.

Member States shall also inform the Commission and ESMA of any subsequent changes with regard to the first subparagraph.

CHAPTER IX

COMPETENT AUTHORITIES

SECTION 1

Designation, powers and redress procedures

Article 44

Designation of competent authorities

Member States shall designate the competent authorities which are to carry out the duties provided for in this Directive.

They shall inform ESMA and the Commission thereof, indicating any division of duties.

The competent authorities shall be public authorities.

Member States shall require that their competent authorities establish the appropriate methods to monitor that AIFMs comply with their obligations under this Directive, where relevant on the basis of guidelines developed by ESMA.

Article 45

Responsibility of competent authorities in Member States

1. The prudential supervision of an AIFM shall be the responsibility of the competent authorities of the home Member State of the AIFM, whether the AIFM manages and/or markets AIFs in another Member State or not, without prejudice to those provisions of this Directive which confer the responsibility for supervision on the competent authorities of the host Member State of the AIFM.

2. The supervision of an AIFM's compliance with Articles 12 and 14 shall be the responsibility of the competent authorities of the host Member State of the AIFM where the AIFM manages and/or markets AIFs through a branch in that Member State.

3. The competent authorities of the host Member State of the AIFM may require an AIFM managing or marketing AIFs in its territory, whether or not through a branch, to provide the information necessary for the supervision of the AIFM's compliance with the applicable rules for which those competent authorities are responsible.

Those requirements shall not be more stringent than those which the host Member State of the AIFM imposes on AIFMs for which it is the home Member State for the monitoring of their compliance with the same rules.

4. Where the competent authorities of the host Member State of the AIFM ascertain that an AIFM managing and/or marketing AIFs in its territory, whether or not through a branch, is in breach of one of the rules in relation to which they have responsibility for supervising compliance, those authorities shall require the AIFM concerned to put an end to that breach and inform the competent authorities of the home Member State thereof.

5. If the AIFM concerned refuses to provide the competent authorities of its host Member State with information falling under their responsibility, or fails to take the necessary steps to put an end to the breach referred to in paragraph 4, the competent authorities of its host Member State shall inform the competent authorities of its home Member State thereof. The competent authorities of the home Member State of the AIFM shall, at the earliest opportunity:

- (a) take all appropriate measures to ensure that the AIFM concerned provides the information requested by the competent authorities of its host Member State pursuant to paragraph 3, or puts an end to the breach referred to in paragraph 4;
- (b) request the necessary information from the relevant supervisory authorities in third countries.

The nature of the measures referred to in point (a) shall be communicated to the competent authorities of the host Member State of the AIFM.

6. If, despite the measures taken by the competent authorities of the home Member State of the AIFM pursuant to paragraph 5 or because such measures prove to be inadequate or are not available in the Member State in question, the AIFM continues to refuse to provide the information requested by the competent authorities of its host Member State pursuant to paragraph 3, or persists in breaching the legal or regulatory provisions, referred to in paragraph 4, in force in its host Member State, the competent authorities of the host Member State of the AIFM may, after informing the competent authorities of the home Member State of the AIFM, take appropriate measures, including those laid down in Articles 46 and 48, to prevent or penalise further irregularities and, in so far as necessary, to prevent that AIFM from initiating any further transactions in its host Member State. Where the function carried out in the host Member State of the AIFM is the management of AIFs, the host Member State may require the AIFM to cease managing those AIFs.

7. Where the competent authorities of the host Member State of the AIFM have clear and demonstrable grounds for believing that the AIFM is in breach of the obligations arising from rules in relation to which they have no responsibility for supervising compliance, they shall refer those findings to the competent authorities of the home Member State of the AIFM which shall take appropriate measures, including, if necessary, request additional information from the relevant supervisory authorities in third countries.

8. If despite the measures taken by the competent authorities of the home Member State of the AIFM or because such measures prove to be inadequate, or because the home Member State of the AIFM fails to act within a reasonable timeframe, the AIFM persists in acting in a manner that is clearly prejudicial to the interests of the investors of the relevant AIF, the financial stability or the integrity of the market in the host Member State of the AIFM, the competent authorities of the host Member State of the AIFM may, after informing the competent authorities of the home Member State of the AIFM, take all appropriate measures needed in order to protect the investors of the relevant AIF, the financial stability and the integrity of the market in the host Member State, including the possibility of preventing the AIFM concerned to further market the units or shares of the relevant AIF in the host Member State.

9. The procedure laid down in paragraphs 7 and 8 shall also apply in the event that the competent authorities of the host Member State have clear and demonstrable grounds for disagreement with the authorisation of a non-EU AIFM by the Member State of reference.

10. Where the competent authorities concerned disagree on any of the measures taken by a competent authority pursuant to paragraphs 4 to 9, they may bring the matter to the attention of ESMA, which may act in accordance with the powers conferred to it under Article 19 of Regulation (EU) No 1095/2010.

11. Where applicable, ESMA shall facilitate the negotiation and conclusion of the cooperation arrangements required by this Directive between the competent authorities of the Member States and the supervisory authorities of third countries.

Article 46

Powers of competent authorities

1. Competent authorities shall be given all supervisory and investigatory powers that are necessary for the exercise of their functions. Such powers shall be exercised in any of the following ways:

- (a) directly;
- (b) in collaboration with other authorities;
- (c) under their responsibility by delegation to entities to which tasks have been delegated;
- (d) by application to the competent judicial authorities.

2. The competent authorities shall have the power to:

- (a) have access to any document in any form and to receive a copy of it;
- (b) require information from any person related to the activities of the AIFM or the AIF and if necessary to summon and question a person with a view to obtaining information;
- (c) carry out on-site inspections with or without prior announcements;
- (d) require existing telephone and existing data traffic records;
- (e) require the cessation of any practice that is contrary to the provisions adopted in the implementation of this Directive;
- (f) request the freezing or the sequestration of assets;
- (g) request the temporary prohibition of professional activity;

- (h) require authorised AIFM, depositaries or auditors to provide information;
- (i) adopt any type of measure to ensure that AIFMs or depositaries continue to comply with the requirements of this Directive applicable to them;
- (j) require the suspension of the issue, repurchase or redemption of units in the interest of the unit-holders or of the public;
- (k) withdraw the authorisation granted to an AIFM or a depositary;
- (l) refer matters for criminal prosecution;
- (m) request that auditors or experts carry out verifications or investigations.

3. Where the competent authority of the Member State of reference considers that an authorised non-EU AIFM is in breach of its obligations under this Directive, it shall notify ESMA, setting out full reasons as soon as possible.

4. Member States shall ensure that the competent authorities have the powers necessary to take all measures required in order to ensure the orderly functioning of markets in those cases where the activity of one or more AIFs in the market for a financial instrument could jeopardise the orderly functioning of that market.

Article 47

Powers and competences of ESMA

1. ESMA may develop and regularly review guidelines for the competent authorities of the Member States on the exercise of their authorisation powers and on the reporting obligations by the competent authorities imposed by this Directive.

ESMA shall further have the powers necessary, including those enumerated in Article 48(3), to carry out the tasks attributed to it by this Directive.

2. The obligation of professional secrecy shall apply to all persons who work or who have worked for ESMA, and for the competent authorities or for any other person to whom ESMA has delegated tasks, including auditors and experts contracted by ESMA. Information covered by professional secrecy shall not be disclosed to another person or authority except where such disclosure is necessary for legal proceedings.

3. All the information exchanged under this Directive between ESMA, the competent authorities, EBA, the European Supervisory Authority (European Insurance and Occupational Pensions Authority) established by Regulation (EU) No 1094/2010 of the European Parliament and of the Council⁽¹⁾ and the ESRB shall be considered confidential, except where ESMA or the competent authority or other authority or body concerned states at the time of communication that such information may be disclosed or where such disclosure is necessary for legal proceedings.

4. In accordance with Article 9 of Regulation (EU) No 1095/2010, ESMA may, where all the conditions in paragraph 5 are met, request the competent authority or competent authorities to take any of the following measures, as appropriate:

- (a) prohibit the marketing in the Union of units or shares of AIFs managed by non-EU AIFMs or of non-EU AIFs managed by EU AIFMs without the authorisation required in Article 37 or without the notification required in Articles 35, 39 and 40 or without being allowed to do so by the relevant Member States in accordance with Article 42;

- (b) impose restrictions on non-EU AIFMs relating to the management of an AIF in case of excessive concentration of risk in a specific market on a cross-border basis;

- (c) impose restrictions on non-EU AIFMs relating to the management of an AIF where its activities potentially constitute an important source of counterparty risk to a credit institution or other systemically relevant institutions.

5. ESMA may take a decision under paragraph 4 and subject to the requirements set out in paragraph 6 if both of the following conditions are met:

- (a) a substantial threat exists, originating or aggravated by the activities of AIFMs, to the orderly functioning and integrity of the financial market or to the stability of the whole or a part of the financial system in the Union and there are cross border implications; and

- (b) the relevant competent authority or competent authorities have not taken measures to address the threat or the measures that have been taken do not sufficiently address the threat.

6. The measures taken by the competent authority or competent authorities pursuant to paragraph 4 shall:

⁽¹⁾ OJ L 331, 15.12.2010, p. 48.

(a) effectively address the threat to the orderly functioning and the integrity of the financial market or to the stability of the whole or a part of the financial system in the Union or significantly improve the ability of competent authorities to monitor the threat;

(b) not create a risk of regulatory arbitrage;

(c) not have a detrimental effect on the efficiency of the financial markets, including reducing liquidity in those markets or creating uncertainty for market participants, in a way that is disproportionate to the benefits of the measures.

7. Before requesting the competent authority to take or renew any measure referred to in paragraph 4, ESMA shall consult, where appropriate, the ESRB and other relevant authorities.

8. ESMA shall notify the competent authorities of the Member State of reference of the non-EU AIFM and the competent authorities of the host Member States of the non-EU AIFM concerned of the decision to request the competent authority or competent authorities to impose or renew any measure referred to in paragraph 4. The notification shall at least specify the following details:

(a) the AIFM and the activities to which the measures apply and their duration;

(b) the reasons why ESMA is of the opinion that it is necessary to impose the measures in accordance with the conditions and requirements set out in this Article, including the evidence in support of those reasons.

9. ESMA shall review its measures referred to in paragraph 4 at appropriate intervals and in any event at least every 3 months. If a measure is not renewed after that 3-month period, it shall automatically expire. Paragraphs 5 to 8 shall apply to a renewal of measures.

10. The competent authorities of the Member State of reference of the non-EU AIFM concerned may request ESMA to reconsider its decision. The procedure set out in the second subparagraph of Article 44(1) of Regulation (EU) No 1095/2010 shall apply.

Article 48

Administrative penalties

1. Member States shall lay down the rules on measures and penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that those rules are enforced. Without prejudice to the procedures for the withdrawal of authorisation or to the right of Member States to impose criminal penalties,

Member States shall ensure, in accordance with their national law, that the appropriate administrative measures can be taken or administrative penalties be imposed against the persons responsible where the provisions adopted in the implementation of this Directive have not been complied with. Member States shall ensure that those measures are effective, proportionate and dissuasive.

2. Member States shall provide that the competent authorities may disclose to the public any measure or penalty that will be imposed for infringement of the provisions adopted in the implementation of this Directive, unless such disclosure would seriously jeopardise the financial markets, be detrimental to the interests of the investors or cause disproportionate damage to the parties involved.

3. ESMA shall draw up an annual report on the application of administrative measures and imposition of penalties in the case of breaches of the provisions adopted in the implementation of this Directive in the different Member States. Competent authorities shall provide ESMA with the necessary information for that purpose.

Article 49

Right of appeal

1. The competent authorities shall give written reasons for any decision to refuse or withdraw authorisation of AIFMs to manage and/or market AIFs, or any negative decision taken in the implementation of the measures adopted in application of this Directive, and communicate them to applicants.

2. Member States shall provide that any decision taken under laws, regulations or administrative provisions adopted in accordance with this Directive is properly reasoned and is the subject of the right of appeal to the courts.

That right of appeal to the courts shall apply also where, in respect of an application for authorisation which provides all the information required, no decision is taken within 6 months of the submission of the application.

SECTION 2

Cooperation between different competent authorities

Article 50

Obligation to cooperate

1. The competent authorities of the Member States shall cooperate with each other and with ESMA and the ESRB whenever necessary for the purpose of carrying out their duties under this Directive or of exercising their powers under this Directive or under national law.

2. Member States shall facilitate the cooperation provided for in this Section.

3. Competent authorities shall use their powers for the purpose of cooperation, even in cases where the conduct under investigation does not constitute an infringement of any regulation in force in their own Member State.

4. The competent authorities of the Member States shall immediately supply one another and ESMA with the information required for the purposes of carrying out their duties under this Directive.

The competent authorities of the home Member State shall forward a copy of the relevant cooperation arrangements entered into by them in accordance with Article 35, 37 and/or 40 to the host Member States of the AIFM concerned. The competent authorities of the home Member State shall, in accordance with procedures relating to the applicable regulatory technical standards referred to in Article 35(14), Article 37(17) or Article 40(14), forward the information received from third-country supervisory authorities in accordance with cooperation arrangements with such supervisory authorities in respect of an AIFM, or, where relevant, pursuant to Article 45(6) or (7), to the competent authorities of host Member State of the AIFM concerned.

Where a competent authority of a host Member State considers that the contents of the cooperation arrangement entered into by the home Member State of the AIFM concerned in accordance with Article 35, 37 and/or 40 does not comply with what is required pursuant to the applicable regulatory technical standards, the competent authorities concerned may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

5. Where the competent authorities of one Member State have clear and demonstrable grounds to suspect that acts contrary to this Directive are being or have been carried out by an AIFM not subject to supervision of those competent authorities, they shall notify ESMA and the competent authorities of the home and host Member States of the AIFM concerned thereof in as specific a manner as possible. The recipient authorities shall take appropriate action, shall inform ESMA and the notifying competent authorities of the outcome of that action and, to the extent possible, of significant interim developments. This paragraph shall be without prejudice to the competences of the notifying competent authority.

6. In order to ensure uniform application of this Directive concerning the exchange of information, ESMA may develop draft implementing technical standards to determine the conditions of application with regard to the procedures for exchange of information between competent authorities and between the competent authorities and ESMA.

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 1095/2010.

Article 51

Transfer and retention of personal data

1. With regard to transfer of personal data between competent authorities, competent authorities shall apply Directive 95/46/EC. With regard to transfer of personal data by ESMA to the competent authorities of a Member State or of a third country, ESMA shall comply with Regulation (EC) No 45/2001.

2. Data shall be retained for a maximum period of 5 years.

Article 52

Disclosure of information to third countries

1. The competent authority of a Member State may transfer to a third country data and the analysis of data on a case-by-case basis where the conditions laid down in Article 25 or 26 of Directive 95/46/EC are met and where the competent authority of the Member State is satisfied that the transfer is necessary for the purpose of this Directive. The third country shall not transfer the data to another third country without the express written authorisation of the competent authority of the Member State.

2. The competent authority of a Member State shall only disclose information received from a competent authority of another Member State to a supervisory authority of a third country where the competent authority of the Member State concerned has obtained express agreement of the competent authority which transmitted the information and, where applicable, the information is disclosed solely for the purposes for which that competent authority gave its agreement.

Article 53

Exchange of information relating to the potential systemic consequences of AIFM activity

1. The competent authorities of the Member States responsible for the authorisation and/or supervision of AIFMs under this Directive shall communicate information to the competent authorities of other Member States where this is relevant for monitoring and responding to the potential implications of the activities of individual AIFMs or AIFMs collectively for the stability of systemically relevant financial institutions and the orderly functioning of markets on which AIFMs are active. ESMA and the ESRB shall also be informed and shall forward this information to the competent authorities of the other Member States.

2. Subject to the conditions laid down in Article 35 of Regulation (EU) No 1095/2010, aggregated information relating to the activities of AIFMs under their responsibility shall be communicated by the competent authorities of the AIFM to ESMA and the ESRB.

3. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying the content of the information to be exchanged pursuant to paragraph 1.

4. The Commission shall adopt implementing acts specifying the modalities and frequency of the information to be exchanged pursuant to paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 59(2).

Article 54

Cooperation in supervisory activities

1. The competent authorities of one Member State may request the cooperation of the competent authorities of another Member State in a supervisory activity or for an on-the-spot verification or in an investigation in the territory of the latter within the framework of their powers pursuant to this Directive.

Where the competent authorities receive a request with respect to an on-the-spot verification or an investigation, it shall perform one of the following:

- (a) carry out the verification or investigation itself;
- (b) allow the requesting authority to carry out the verification or investigation;
- (c) allow auditors or experts to carry out the verification or investigation.

2. In the case referred to in point (a) of paragraph 1 the competent authority of the Member State which has requested cooperation may ask that members of its own personnel assist the personnel carrying out the verification or investigation. The verification or investigation shall, however, be the subject of the overall control of the Member State on whose territory it is conducted.

In the case referred to in point (b) of paragraph 1 the competent authority of the Member State on whose territory the verification or investigation is carried out may request that members of its own personnel assist the personnel carrying out the verification or investigation.

3. Competent authorities may refuse to exchange information or to act on a request for cooperation in carrying out an investigation or on-the-spot verification only in the following cases:

- (a) the investigation, on-the-spot verification or exchange of information might adversely affect the sovereignty, security or public order of the Member State addressed;

(b) judicial proceedings have already been initiated in respect of the same actions and the same persons before the authorities of the Member State addressed;

(c) final judgment has already been delivered in the Member State addressed in respect of the same persons and the same actions.

The competent authorities shall inform the requesting competent authorities of any decision taken under the first subparagraph, stating the reasons therefor.

4. In order to ensure uniform application of this Article, ESMA may develop draft implementing technical standards to establish common procedures for competent authorities to cooperate in on-the-spot verifications and investigations.

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 1095/2010.

Article 55

Dispute settlement

In case of disagreement between competent authorities of Member States on an assessment, action or omission of one competent authority in areas where this Directive requires cooperation or coordination between competent authorities from more than one Member State, competent authorities may refer the matter to the ESMA which may act in accordance with the powers conferred on it under Article 19 of Regulation (EU) No 1095/2010.

CHAPTER X

TRANSITIONAL AND FINAL PROVISIONS

Article 56

Exercise of the delegation

1. The powers to adopt delegated acts referred to in Articles 3, 4, 9, 12, 14 to 25, 34 to 37, 40, 42, 53, 67 and 68 shall be conferred on the Commission for a period of 4 years from 21 July 2011. The Commission shall draw up a report in respect of the delegated powers no later than 6 months before the end of the 4-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 57.

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

3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions of Articles 57 and 58.

*Article 57***Revocation of the delegation**

1. The delegation of power referred to in Articles 3, 4, 9, 12, 14 to 25, 34 to 37, 40, 42, 53, 67 and 68 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and the possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

*Article 58***Objections to delegated acts**

1. The European Parliament and the Council may object to a delegated act within a period of 3 months from the date of notification. At the initiative of the European Parliament or the Council that period shall be extended by 3 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the *Official Journal of the European Union* and shall enter into force at the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if, upon a justified request by the Commission, the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If either the European Parliament or the Council objects to the adopted delegated act within the period referred to in paragraph 1, it shall not enter into force. In accordance with Article 296 TFEU, the institution which objects shall state the reasons for objecting to the delegated act.

*Article 59***Implementing measures**

1. The Commission shall be assisted by the European Securities Committee established by Commission Decision 2001/528/EC⁽¹⁾. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

*Article 60***Disclosure of derogations**

Where a Member State makes use of a derogation or option provided by Articles 6, 9, 21, 22, 28, 43 and Article 61(5), it shall inform the Commission thereof as well as of any subsequent changes. The Commission shall make the information public on a web-site or by other easily accessible means.

*Article 61***Transitional provisions**

1. AIFMs performing activities under this Directive before 22 July 2013 shall take all necessary measures to comply with national law stemming from this Directive and shall submit an application for authorisation within 1 year of that date.

2. Articles 31, 32 and 33 shall not apply to the marketing of units or shares of AIFs that are subject to a current offer to the public under a prospectus that has been drawn up and published in accordance with Directive 2003/71/EC before 22 July 2013 for the duration of validity of that prospectus.

3. AIFMs in so far as they manage AIFs of the closed-ended type before 22 July 2013 which do not make any additional investments after 22 July 2013 may however continue to manage such AIFs without authorisation under this Directive.

4. AIFMs in so far as they manage AIFs of the closed-ended type whose subscription period for investors has closed prior to the entry into force of this Directive and are constituted for a period of time which expires at the latest 3 years after 22 July 2013, may, however, continue to manage such AIFs without needing to comply with this Directive except for Article 22 and, where relevant, Articles 26 to 30, or to submit an application for authorisation under this Directive.

5. The competent authorities of the home Member State of an AIF or in case where the AIF is not regulated the competent authorities of the home Member State of an AIFM may allow institutions referred to in point (a) of Article 21(3) and established in another Member State to be appointed as a depositary until 22 July 2017. This provision shall be without prejudice to the full application of Article 21, with the exception of point (a) of paragraph 5 of that Article on the place where the depositary is to be established.

⁽¹⁾ OJ L 191, 13.7.2001, p. 45.

Article 62

Amendments to Directive 2003/41/EC

Directive 2003/41/EC is amended as follows:

(1) in Article 2(2), point (b) is replaced by the following:

'(b) institutions which are covered by Directives 73/239/EEC (*), 85/611/EEC (**), 93/22/EEC (***), 2000/12/EC (****), 2002/83/EC (*****) and 2011/61/EU (*****);

(*) 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).

(**) Council Directive 85/611/EEC of 20 December 1985 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) (OJ L 375, 31.12.1985, p. 3).

(***) Council Directive 93/22/EEC of 10 May 1993 on investment services in the securities field (OJ L 141, 11.6.1993, p. 27).

(****) Directive 2000/12/EC of the European Parliament and of the Council of 20 March 2000 relating to the taking-up and pursuit of the business of credit institutions (OJ L 126, 26.5.2000, p. 1).

(*****) 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).

(*****) Directive 2011/61/EU of the European Parliament and of the Council of 8 June 2011 on Alternative Investment Fund Managers (OJ L 174, 1.7.2011, p. 1);

(2) Article 19(1) is replaced by the following:

'1. Member States shall not restrict institutions from appointing, for the management of the investment portfolio, investment managers established in another Member State and duly authorised for this activity, in accordance with Directives 85/611/EEC, 93/22/EEC, 2000/12/EC, 2002/83/EC and 2011/61/EU, as well as those referred to in Article 2(1) of this Directive.'

Article 63

Amendments to Directive 2009/65/EC

Directive 2009/65/EC is amended as follows:

(1) the following Article is inserted:

Article 50a

In order to ensure cross-sectoral consistency and to remove misalignment between the interest of firms that repackage loans into tradable securities and other financial instruments (originators) and UCITS that invest in those securities or other financial instruments, the Commission shall adopt, by means of delegated acts in accordance with Article 112a and subject to conditions of Articles 112b and 112c, measures laying down the requirements in the following areas:

(a) the requirements that need to be met by the originator in order for a UCITS to be allowed to invest in securities or other financial instruments of this type issued after 1 January 2011, including requirements that ensure that the originator retains a net economic interest of not less than 5 %;

(b) qualitative requirements that must be met by UCITS which invest in those securities or other financial instruments.;

(2) Article 112(2) is replaced by the following:

'2. The power to adopt the delegated acts referred to in Articles 12, 14, 23, 33, 43, 51, 60, 61, 62, 64, 75, 78, 81, 95 and 111 shall be conferred on the Commission for a period of 4 years from 4 January 2011. The power to adopt the delegated acts referred to in Article 50a shall be conferred on the Commission for a period of 4 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 4-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes them in accordance with Article 112a.;

(3) Article 112a(1) is replaced by the following:

'1. The delegation of power referred to in Articles 12, 14, 23, 33, 43, 50a, 51, 60, 61, 62, 64, 75, 78, 81, 95 and 111 may be revoked at any time by the European Parliament or by the Council.'

Article 64

Amendment to Regulation (EC) No 1060/2009

In Regulation (EC) No 1060/2009, the first paragraph of Article 4(1) is replaced by the following:

'1. Credit institutions as defined in Directive 2006/48/EC, investment firms as defined in Directive 2004/39/EC, insurance undertakings subject to the First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the take-up and pursuit of the business of direct insurance other than life assurance (*), assurance undertakings as defined in Directive 2002/83/EC of the European Parliament and of the Council of 5 November 2002 concerning life assurance (**), reinsurance undertakings as defined in Directive 2005/68/EC of the European Parliament and of the Council of 16 November 2005 on reinsurance (***), UCITS as defined in Directive 2009/65/EC of the European

Parliament and of the Council of 13 July 2009 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) (****), institutions for occupational retirement provision as defined in Directive 2003/41/EC and alternative investment funds as defined in Directive 2011/61/EU of the European Parliament and of the Council of 8 June 2011 on Alternative Investment Fund Managers (*****) may use credit ratings for regulatory purposes only if they are issued by credit rating agencies established in the Union and registered in accordance with this Regulation.

(*) OJ L 228, 16.8.1973, p. 3.

(**) OJ L 345, 19.12.2002, p. 1.

(***) OJ L 323, 9.12.2005, p. 1.

(****) OJ L 302, 17.11.2009, p. 32.

(*****) OJ L 174, 1.7.2011, p. 1.

Article 65

Amendment to Regulation (EU) No 1095/2010

In Article 1(2) of Regulation (EU) No 1095/2010, the words 'any future legislation in the area of Alternative Investment Fund Managers (AIFM)' are replaced by the words 'Directive 2011/61/EU of the European Parliament and of the Council of 8 June 2011 on Alternative Investment Fund Managers (*)

(*) OJ L 174, 1.7.2011, p. 1.

Article 66

Transposition

1. By 22 July 2013, Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

2. Member States shall apply the laws, regulations and administrative provisions referred to in paragraph 1 from 22 July 2013.

3. Notwithstanding paragraph 2, Member States shall apply the laws, regulations and administrative provisions necessary to comply with Article 35 and Articles 37 to 41 in accordance with the delegated act adopted by the Commission pursuant to Article 67(6) and from the date specified therein.

4. Member States shall ensure that the laws, regulations and administrative provisions adopted by them in compliance with Articles 36 and 42 cease to apply in accordance with the delegated act adopted by the Commission pursuant to Article 68(6) and on the date specified therein.

5. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication.

6. 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 67

Delegated act on the application of Article 35 and Articles 37 to 41

1. By 22 July 2015, ESMA shall issue to, the European Parliament, the Council and the Commission:

(a) an opinion on the functioning of the passport for EU AIFMs managing and/or marketing EU AIFs pursuant to Articles 32 and 33 and on the functioning of the marketing of non-EU AIFs by EU AIFMs in the Member States and the management and/or marketing of AIFs by non-EU AIFMs in the Member States pursuant to the applicable national regimes set out in Articles 36 and 42; and

(b) advice on the application of the passport to the marketing of non-EU AIFs by EU AIFMs in the Member States and the management and/or marketing of AIFs by non-EU AIFMs in the Member States in accordance with the rules set out in Article 35 and Articles 37 to 41.

2. ESMA shall base its opinion and advice on the application of the passport to the marketing of non-EU AIFs by EU AIFMs in the Member States and the management and/or marketing of AIFs by non-EU AIFMs in the Member States, inter alia, on:

(a) as regards the functioning of the passport for EU AIFMs managing and/or marketing EU AIFs:

(i) the use made of the passport;

(ii) the problems encountered regarding:

— effective cooperation among competent authorities,

— effective functioning of the notification system,

- investor protection,
 - mediation by ESMA, including the number of cases and the effectiveness of the mediation;
- (iii) the effectiveness of the collection and sharing of information in relation to the monitoring of systemic risks by national competent authorities, ESMA and ESRB;
- (b) as regards the functioning of the marketing of non-EU AIFs by EU AIFMs in the Member States and the management and/or marketing of AIFs by non-EU AIFMs in the Member States in accordance with the applicable national regimes:
- (i) compliance of EU AIFMs with all the requirements established in this Directive with the exception of Article 21;
 - (ii) compliance of non-EU AIFMs with Articles 22, 23 and 24 in respect of each AIF marketed by the AIFM and, where relevant, with Articles 26 to 30;
 - (iii) existence and effectiveness of cooperation arrangements for the purpose of systemic risk oversight and in line with international standards between the competent authorities of the Member State where the AIFs are marketed, in so far as applicable, the competent authorities of the home Member State of the EU AIF and the supervisory authorities of the third country where the non-EU AIFM is established and, in so far as applicable, the supervisory authorities of the third country where the non-EU AIF is established;
 - (iv) any issues relating to investor protection that might have occurred;
 - (v) any features of a third-country regulatory and supervisory framework which might prevent the effective exercise by the competent authorities of their supervisory functions under this Directive;
- (c) as regards the functioning of both systems, the potential market disruptions and distortions in competition (level playing field) or any general or specific difficulties which EU AIFMs encounter in establishing themselves or marketing AIFs they manage in any third country.

3. To that end, as from the entry into force of the national laws, regulations and administrative provisions necessary to comply with this Directive and until the issuance of the opinion of ESMA referred to in point (a) of paragraph 1, the competent authorities of the Member States shall, quarterly, provide ESMA with information on the AIFMs that are managing and/or marketing AIFs under their supervision,

either under the application of the passport regime provided for in this Directive or under their national regimes, and with information needed for the assessment of the elements referred to in paragraph 2.

4. Where ESMA considers that there are no significant obstacles regarding investor protection, market disruption, competition and the monitoring of systemic risk, impeding the application of the passport to the marketing of non-EU AIFs by EU AIFMs in the Member States and the management and/or marketing of AIFs by non-EU AIFMs in the Member States in accordance with the rules set out in Article 35 and Articles 37 to 41, it shall issue positive advice in this regard.

5. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying the contents of the information to be provided pursuant to paragraph 2.

6. The Commission shall adopt a delegated act within 3 months after having received positive advice and an opinion from ESMA, and taking into account the criteria listed in paragraph 2 and the objectives of this Directive, such as those relating to the internal market, investor protection and the effective monitoring of systemic risk, in accordance with Article 56 and subject to the conditions of Articles 57 and 58, specifying the date when the rules set out in Article 35 and Articles 37 to 41 become applicable in all Member States.

If there is objection to the delegated act referred to in the first subparagraph in accordance with Article 58, the Commission shall re-adopt the delegated act pursuant to which the rules set out in Article 35 and Articles 37 to 41 shall become applicable in all Member States, in accordance with Article 56 and subject to the conditions of Articles 57 and 58, at a later stage which seems appropriate to it, taking into account the criteria listed in paragraph 2 and the objectives of this Directive, such as those relating to the internal market, investor protection and the effective monitoring of systemic risk.

7. If ESMA has not issued its advice within the time limit referred to in paragraph 1, the Commission shall request the advice to be provided within a new time limit.

Article 68

Delegated act on the termination of the application of Articles 36 and 42

1. 3 years after the entry into force of the delegated act referred to in Article 67(6) pursuant to which the rules set out in Article 35 and Articles 37 to 41 have become applicable in all Member States, ESMA shall issue to the European Parliament, the Council and the Commission:

- (a) an opinion on the functioning of the passport for EU AIFMs marketing non-EU AIFs in the Union pursuant to Article 35 and for non-EU AIFMs managing and/or marketing AIFs in the Union pursuant to Articles 37 to 41, and on the functioning of the marketing of non-EU AIFs by EU AIFMs in the Member States and the management and/or marketing of AIFs by non-EU AIFMs in the Member States pursuant to the applicable national regimes as set out in Articles 36 and 42; and
- (b) advice on the termination of the existence of the national regimes set out in Articles 36 and 42 in parallel with the existence of the passport in accordance with the rules set out in Article 35 and Articles 37 to 41.
2. ESMA shall base its opinion and advice on the termination of the existence of the national regimes set out in Articles 36 and 42 inter alia:
- (a) as regards the functioning of the passport for EU AIFMs marketing non-EU AIFs in the Union and for non-EU AIFMs managing and/or marketing AIFs in the Union:
- (i) the use made of the passport;
 - (ii) the problems encountered regarding:
 - effective cooperation among competent authorities,
 - effective functioning of the notification system,
 - the indication of the Member State of reference,
 - the effective exercise by the competent authorities of their supervisory functions being prevented by the laws, regulations or administrative provisions of a third country governing AIFMs, or by limitations in the supervisory and investigatory powers of the third country supervisory authorities,
 - investor protection,
 - investor access in the Union,
 - the impact on developing countries,
 - mediation by ESMA, including the number of cases and the effectiveness of the mediation;
- (iii) the negotiation, conclusion, existence and effectiveness of the required cooperation arrangements;
- (iv) the effectiveness of the collection and sharing of information in relation to the monitoring of systemic risks by national competent authorities, ESMA and the ESRB;
- (v) results of peer reviews referred to in Article 38;
- (b) as regards the functioning of the marketing of non-EU AIFs by EU AIFMs in the Member States and the management and/or marketing of AIFs by non-EU AIFMs in the Member States in accordance with the applicable national regimes:
- (i) compliance of EU AIFMs with all the requirements established in this Directive with the exception of Article 21;
 - (ii) compliance of non-EU AIFMs with Articles 22, 23 and 24 in respect of each AIF marketed by the AIFM and, where relevant, with Articles 26 to 30;
 - (iii) existence and effectiveness of cooperation arrangements for the purpose of systemic risk oversight and in line with international standards between the competent authorities of the Member State where the AIFs are marketed, in so far as applicable, the competent authorities of the home Member State of the EU AIF concerned and the supervisory authorities of the third country where the non-EU AIFM is established and, in so far as applicable, the supervisory authorities of the third country where the non-EU AIF is established;
 - (iv) any issues relating to investor protection that might have occurred;
 - (v) any features of a third country regulatory and supervisory framework which might prevent the effective exercise by the competent authorities of the Union of their supervisory functions under this Directive;
- (c) as regards the functioning of both systems, the potential market disruptions and distortions in competition (level playing field) and any potential negative effect on investor access or investment in or for the benefit of developing countries;

(d) a quantitative assessment identifying the number of third-country jurisdictions in which there is established an AIFM that is marketing an AIF in a Member State either under the application of the passport regime referred to in Article 40 or under the national regimes referred to in Article 42.

3. To that end, as from the entry into force of the delegated act referred to in Article 67(6) and until the issuance of the ESMA opinion referred to in point (a) of paragraph 1 of this Article, the competent authorities shall, quarterly, provide ESMA with information on the AIFMs that are managing and/or marketing AIFs under their supervision, either under the application of the passport regime provided for in this Directive, or under their national regimes.

4. If ESMA considers that there are no significant obstacles regarding investor protection, market disruption, competition or the monitoring of systemic risk, impeding the termination of the national regimes pursuant to Articles 36 and 42 and making the passport for the marketing of non-EU AIFs by EU AIFMs in the Union and the management and/or marketing of AIFs by non-EU AIFM in the Union in accordance with the rules set out in Article 35 and Articles 37 to 41 the sole possible regime for such activities by the relevant AIFMs in the Union, it shall issue positive advice in this regard.

5. The Commission shall adopt, by means of delegated acts in accordance with Article 56 and subject to the conditions of Articles 57 and 58, measures specifying the contents of the information to be provided pursuant to paragraph 2.

6. The Commission shall adopt a delegated act within 3 months after having received positive advice and an opinion from ESMA and taking into account the criteria listed in paragraph 2 and the objectives of this Directive, such as those relating to the internal market, investor protection and the effective monitoring of systemic risk, in accordance with Article 56 and subject to the conditions of Articles 57 and 58, specifying the date when the national regimes set out in Articles 36 and 42 are to be terminated and the passport regime provided for in Article 35 and Articles 37 to 41 shall become the sole and mandatory regime applicable in all Member States.

If there is objection to the delegated act referred to in the first subparagraph in accordance with Article 58, the Commission shall re-adopt the delegated act pursuant to which the national regimes set out in Articles 36 and 42 are to be terminated and the passport regime provided for in Article 35 and Articles 37 to 41 shall become the sole and mandatory regime applicable in all Member States, in accordance with Article 56 and subject to the conditions of Articles 57 and 58, at a later stage which seems appropriate to it, taking into account the criteria listed in

paragraph 2 and the objectives of this Directive, such as those relating to the internal market, investor protection and the effective monitoring of systemic risk.

7. If ESMA has not issued its advice within the time limit referred to in paragraph 1, the Commission shall request the advice to be provided within a new time limit.

Article 69

Review

1. By 22 July 2017, the Commission shall, on the basis of public consultation and in the light of the discussions with competent authorities, start a review on the application and the scope of this Directive. That review shall analyse the experience acquired in applying this Directive, its impact on investors, AIFs or AIFMs, in the Union and in third countries, and the degree to which the objectives of this Directive have been achieved. The Commission shall, if necessary, propose appropriate amendments. The review shall include a general survey of the functioning of the rules in this Directive and the experience acquired in applying them, including:

- (a) the marketing by EU AIFMs of non-EU AIFs in the Member States taking place through national regimes;
- (b) the marketing of AIFs in the Member States by non-EU AIFMs taking place through national regimes;
- (c) the management and marketing of AIFs in the Union by AIFMs authorised in accordance with this Directive taking place through the passport regime provided for in this Directive;
- (d) the marketing of AIFs in the Union by or on behalf of persons or entities other than AIFMs;
- (e) the investment into AIFs by or on behalf of European professional investors;
- (f) the impact of the depositary rules set out in Article 21 on the depositary market in the Union;
- (g) the impact of the transparency and reporting requirements set out in Articles 22 to 24, 28 and 29 on the assessment of systemic risk;
- (h) the potential adverse impact on retail investors;
- (i) the impact of this Directive on the operation and viability of the private equity and venture capital funds;
- (j) the impact of this Directive on the investor access in the Union;

- (k) the impact of this Directive on investment in or for the benefit of developing countries;
- (l) the impact of this Directive on the protection of non-listed companies or issuers provided by Articles 26 to 30 of this Directive and on the level playing field between AIFs and other investors after the acquisition of major holdings in or control over such non-listed companies or issuers.

When reviewing marketing and/or management of AIFs referred to in points (a), (b) and (c) of the first subparagraph, the Commission shall analyse the appropriateness of entrusting ESMA with further supervisory responsibilities in this area.

2. For the purposes of the review referred to in paragraph 1, Member States shall provide the Commission annually with information on the AIFMs that are managing and/or marketing AIFs under their supervision, either under the passport regime provided for in this Directive, or under their national regimes, with an indication of the date on which the passport regime has been transposed and, if relevant, applied, in their jurisdiction.

ESMA shall provide the Commission with information on all the non-EU AIFMs that have been authorised or have requested authorisation in accordance with Article 37.

The information referred to in the first and second subparagraphs shall include:

- (a) information on where the AIFMs concerned are established;
- (b) if applicable, identification of the EU AIFs managed and/or marketed by them;
- (c) if applicable, identification of the non-EU AIFs managed by EU AIFMs but not marketed in the Union;
- (d) if applicable, identification of the non-EU AIFs marketed in the Union;

- (e) information on the applicable regime, whether national or Union, under which the relevant AIFMs are performing their activities; and
- (f) any other information relevant to the understanding of how the management and the marketing of AIFs by AIFMs in the Union operates in practice.

3. The review referred to in paragraph 1 shall take due account of developments at international level and discussions with third countries and international organisations.

4. After finalising its review, the Commission shall, without undue delay, submit a report to the European Parliament and the Council. If appropriate, the Commission shall make proposals, including amendments to this Directive, taking into account the objectives of this Directive and its effects on investor protection, market disruption and competition, the monitoring of systemic risk and potential impacts on investors, AIFs or AIFMs in the Union and in third countries.

Article 70

Entry into force

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

Article 71

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 8 June 2011.

For the European Parliament
The President
J. BUZEK

For the Council
The President
GYŐRI E.

ANNEX I

1. Investment management functions which an AIFM shall at least perform when managing an AIF:
 - (a) portfolio management;
 - (b) risk management.
 2. Other functions that an AIFM may additionally perform in the course of the collective management of an AIF:
 - (a) Administration:
 - (i) legal and fund management accounting services;
 - (ii) customer inquiries;
 - (iii) valuation and pricing, including tax returns;
 - (iv) regulatory compliance monitoring;
 - (v) maintenance of unit-/shareholder register;
 - (vi) distribution of income;
 - (vii) unit/shares issues and redemptions;
 - (viii) contract settlements, including certificate dispatch;
 - (ix) record keeping;
 - (b) Marketing;
 - (c) Activities related to the assets of AIFs, namely services necessary to meet the fiduciary duties of the AIFM, facilities management, real estate administration activities, advice to undertakings on capital structure, industrial strategy and related matters, advice and services relating to mergers and the purchase of undertakings and other services connected to the management of the AIF and the companies and other assets in which it has invested.
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ANNEX II

REMUNERATION POLICY

1. When establishing and applying the total remuneration policies, inclusive of salaries and discretionary pension benefits, for those categories of staff, including senior management, risk takers, control functions and any employee receiving total remuneration that takes them into the same remuneration bracket as senior management and risk takers, whose professional activities have a material impact on the risk profiles of the AIFMs or of AIFs they manage, AIFMs shall comply with the following principles in a way and to the extent that is appropriate to their size, internal organisation and the nature, scope and complexity of their activities:
 - (a) the remuneration policy is consistent with and promotes sound and effective risk management and does not encourage risk-taking which is inconsistent with the risk profiles, rules or instruments of incorporation of the AIFs they manage;
 - (b) the remuneration policy is in line with the business strategy, objectives, values and interests of the AIFM and the AIFs it manages or the investors of such AIFs, and includes measures to avoid conflicts of interest;
 - (c) the management body of the AIFM, in its supervisory function, adopts and periodically reviews the general principles of the remuneration policy and is responsible for its implementation;
 - (d) the implementation of the remuneration policy is, at least annually, subject to central and independent internal review for compliance with policies and procedures for remuneration adopted by the management body in its supervisory function;
 - (e) staff engaged in control functions are compensated in accordance with the achievement of the objectives linked to their functions, independent of the performance of the business areas they control;
 - (f) the remuneration of the senior officers in the risk management and compliance functions is directly overseen by the remuneration committee;
 - (g) where remuneration is performance related, the total amount of remuneration is based on a combination of the assessment of the performance of the individual and of the business unit or AIF concerned and of the overall results of the AIFM, and when assessing individual performance, financial as well as non-financial criteria are taken into account;
 - (h) the assessment of performance is set in a multi-year framework appropriate to the life-cycle of the AIFs managed by the AIFM in order to ensure that the assessment process is based on longer term performance and that the actual payment of performance-based components of remuneration is spread over a period which takes account of the redemption policy of the AIFs it manages and their investment risks;
 - (i) guaranteed variable remuneration is exceptional, occurs only in the context of hiring new staff and is limited to the first year;
 - (j) fixed and variable components of total remuneration are appropriately balanced and the fixed component represents a sufficiently high proportion of the total remuneration to allow the operation of a fully flexible policy, on variable remuneration components, including the possibility to pay no variable remuneration component;
 - (k) payments related to the early termination of a contract reflect performance achieved over time and are designed in a way that does not reward failure;
 - (l) the measurement of performance used to calculate variable remuneration components or pools of variable remuneration components includes a comprehensive adjustment mechanism to integrate all relevant types of current and future risks;
 - (m) subject to the legal structure of the AIF and its rules or instruments of incorporation, a substantial portion, and in any event at least 50 % of any variable remuneration consists of units or shares of the AIF concerned, or equivalent ownership interests, or share-linked instruments or equivalent non-cash instruments, unless the management of AIFs accounts for less than 50 % of the total portfolio managed by the AIFM, in which case the minimum of 50 % does not apply.

The instruments referred to in this point shall be subject to an appropriate retention policy designed to align incentives with the interests of the AIFM and the AIFs it manages and the investors of such AIFs. Member States or their competent authorities may place restrictions on the types and designs of those instruments or ban certain instruments as appropriate. This point shall be applied to both the portion of the variable remuneration component deferred in line with point (n) and the portion of the variable remuneration component not deferred;

- (n) a substantial portion, and in any event at least 40 %, of the variable remuneration component, is deferred over a period which is appropriate in view of the life cycle and redemption policy of the AIF concerned and is correctly aligned with the nature of the risks of the AIF in question.

The period referred to in this point shall be at least three to 5 years unless the life cycle of the AIF concerned is shorter; remuneration payable under deferral arrangements vests no faster than on a pro-rata basis; in the case of a variable remuneration component of a particularly high amount, at least 60 % of the amount is deferred;

- (o) the variable remuneration, including the deferred portion, is paid or vests only if it is sustainable according to the financial situation of the AIFM as a whole, and justified according to the performance of the business unit, the AIF and the individual concerned.

The total variable remuneration shall generally be considerably contracted where subdued or negative financial performance of the AIFM or of the AIF concerned occurs, taking into account both current compensation and reductions in payouts of amounts previously earned, including through malus or clawback arrangements;

- (p) the pension policy is in line with the business strategy, objectives, values and long-term interests of the AIFM and the AIFs it manages.

If the employee leaves the AIFM before retirement, discretionary pension benefits shall be held by the AIFM for a period of 5 years in the form of instruments defined in point (m). In the case of an employee reaching retirement, discretionary pension benefits shall be paid to the employee in the form of instruments defined in point (m), subject to a 5 year retention period;

- (q) staff are required to undertake not to use personal hedging strategies or remuneration- and liability-related insurance to undermine the risk alignment effects embedded in their remuneration arrangements;

- (r) variable remuneration is not paid through vehicles or methods that facilitate the avoidance of the requirements of this Directive.

2. The principles set out in paragraph 1 shall apply to remuneration of any type paid by the AIFM, to any amount paid directly by the AIF itself, including carried interest, and to any transfer of units or shares of the AIF, made to the benefits of those categories of staff, including senior management, risk takers, control functions and any employee receiving total remuneration that takes them into the same remuneration bracket as senior management and risk takers, whose professional activities have a material impact on their risk profile or the risk profiles of the AIF that they manage.

3. AIFMs that are significant in terms of their size or the size of the AIFs they manage, their internal organisation and the nature, the scope and the complexity of their activities shall establish a remuneration committee. The remuneration committee shall be constituted in a way that enables it to exercise competent and independent judgment on remuneration policies and practices and the incentives created for managing risk.

The remuneration committee shall be responsible for the preparation of decisions regarding remuneration, including those which have implications for the risk and risk management of the AIFM or the AIF concerned and which are to be taken by the management body in its supervisory function. The remuneration committee shall be chaired by a member of the management body who does not perform any executive functions in the AIFM concerned. The members of the remuneration committee shall be members of the management body who do not perform any executive functions in the AIFM concerned.

ANNEX III

DOCUMENTATION AND INFORMATION TO BE PROVIDED IN CASE OF INTENDED MARKETING IN THE HOME MEMBER STATE OF THE AIFM

- (a) A notification letter, including a programme of operations identifying the AIFs the AIFM intends to market and information on where the AIFs are established;
 - (b) the AIF rules or instruments of incorporation;
 - (c) identification of the depositary of the AIF;
 - (d) a description of, or any information on, the AIF available to investors;
 - (e) information on where the master AIF is established if the AIF is a feeder AIF;
 - (f) any additional information referred to in Article 23(1) for each AIF the AIFM intends to market;
 - (g) where relevant, information on the arrangements established to prevent units or shares of the AIF from being marketed to retail investors, including in the case where the AIFM relies on activities of independent entities to provide investment services in respect of the AIF.
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ANNEX IV

DOCUMENTATION AND INFORMATION TO BE PROVIDED IN THE CASE OF INTENDED MARKETING IN MEMBER STATES OTHER THAN THE HOME MEMBER STATE OF THE AIFM

- (a) A notification letter, including a programme of operations identifying the AIFs the AIFM intends to market and information on where the AIFs are established;
 - (b) the AIF rules or instruments of incorporation;
 - (c) identification of the depositary of the AIF;
 - (d) a description of, or any information on, the AIF available to investors;
 - (e) information on where the master AIF is established if the AIF is a feeder AIF;
 - (f) any additional information referred to in Article 23(1) for each AIF the AIFM intends to market;
 - (g) the indication of the Member State in which it intends to market the units or shares of the AIF to professional investors;
 - (h) information about arrangements made for the marketing of AIFs and, where relevant, information on the arrangements established to prevent units or shares of the AIF from being marketed to retail investors, including in the case where the AIFM relies on activities of independent entities to provide investment services in respect of the AIF.
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DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

(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, and point (c) of Article 168(4), thereof,

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) Directive 2001/83/EC of the European Parliament and of the Council ⁽⁴⁾ lays down the rules for, inter alia, manufacturing, importing, placing on the market, and the wholesale distribution of medicinal products in the Union as well as rules relating to active substances.
- (2) There is an alarming increase of medicinal products detected in the Union which are falsified in relation to their identity, history or source. Those products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients, including active substances, in the wrong dosage thus posing an important threat to public health.
- (3) Past experience shows that such falsified medicinal products do not reach patients only through illegal means, but via the legal supply chain as well. This poses a particular threat to human health and may lead to a lack of trust of the patient also in the legal supply chain. Directive 2001/83/EC should be amended in order to respond to this increasing threat.
- (4) The threat to public health is also recognised by the World Health Organisation (WHO), which set up the International Medical Products Anti-Counterfeiting Taskforce ('IMPACT'). IMPACT developed Principles and Elements for National Legislation against Counterfeit Medical Products, which were endorsed by the IMPACT General Meeting in Lisbon on 12 December 2007. The Union participated actively in IMPACT.
- (5) A definition of 'falsified medicinal product' should be introduced in order to clearly distinguish falsified

medicinal products from other illegal medicinal products, as well as from products infringing intellectual property rights. Furthermore, medicinal products with unintentional quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products. To ensure uniform application of this Directive, the terms 'active substance' and 'excipient' should also be defined.

- (6) Persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining a wholesale distribution authorisation in accordance with Directive 2001/83/EC. However, today's distribution network for medicinal products is increasingly complex and involves many players who are not necessarily wholesale distributors as referred to in that Directive. In order to ensure the reliability of the supply chain, legislation in relation to medicinal products should address all actors in the supply chain. This includes not only wholesale distributors, whether or not they physically handle the medicinal products, but also brokers who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products.
- (7) Falsified active substances and active substances that do not comply with applicable requirements of Directive 2001/83/EC pose serious risks to public health. Those risks should be addressed by strengthening the verification requirements applicable to the manufacturer of the medicinal product.
- (8) There is a range of different good manufacturing practices that are suitable for being applied to the manufacturing of excipients. In order to provide for a high level of protection of public health, the manufacturer of the medicinal product should assess the suitability of excipients on the basis of appropriate good manufacturing practices for excipients.
- (9) In order to facilitate enforcement of and control of compliance with Union rules relating to active substances, the manufacturers, importers or distributors of those substances should notify the competent authorities concerned of their activities.
- (10) Medicinal products may be introduced into the Union while not being intended to be imported, i.e. not intended to be released for free circulation. If those medicinal products are falsified they present a risk to public health within the Union. In addition, those falsified medicinal products may reach patients in third countries. Member States should take measures to prevent these falsified medicinal products, if introduced

⁽¹⁾ OJ C 317, 23.12.2009, p. 62.

⁽²⁾ OJ C 79, 27.3.2010, p. 50.

⁽³⁾ Position of the European Parliament of 16 February 2011 (not yet published in the Official Journal) and decision of the Council of 27 May 2011.

⁽⁴⁾ OJ L 311, 28.11.2001, p. 67.

into the Union, from entering into circulation. When adopting provisions supplementing this obligation on Member States to take those measures, the Commission should take account of the administrative resources available and the practical implications, as well as the need to maintain swift trade flows for legitimate medicinal products. Those provisions should be without prejudice to customs legislation, to the distribution of competences between the Union and the Member States and to the distribution of responsibilities within Member States.

- (11) Safety features for medicinal products should be harmonised within the Union in order to take account of new risk profiles, while ensuring the functioning of the internal market for medicinal products. Those safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering. The scope of these safety features should take due account of the particularities of certain medicinal products or categories of medicinal products, such as generic medicinal products. Medicinal products subject to prescription should as a general rule bear the safety features. However, in view of the risk of falsification and the risk arising from falsification of medicinal products or categories of medicinal products there should be the possibility to exclude certain medicinal products or categories of medicinal products subject to prescription from the requirement to bear the safety features by way of a delegated act, following a risk assessment. Safety features should not be introduced for medicinal products or categories of medicinal products not subject to prescription unless, by way of exception, an assessment shows the risk of falsification, which leads to serious consequences. Those medicinal products should accordingly be listed in a delegated act.

The risk assessments should consider aspects such as the price of the medicinal product; previous cases of falsified medicinal products being reported in the Union and in third countries; the implications of a falsification for public health, taking into account the specific characteristics of the products concerned; and the severity of the conditions intended to be treated. The safety features should allow the verification of each supplied pack of the medicinal products, regardless of how they are supplied including through sale at a distance. The unique identifier as well as the corresponding repositories system should apply without prejudice to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁽¹⁾ and should retain clear and effective safeguards whenever personal data is processed. The repositories system containing information on safety features might include commercially sensitive information. This information must be appropriately protected. When introducing the obligatory safety features, due account should be taken of the particular characteristics of the supply chains in Member States.

- (12) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing auth-

orisation. In order for the safety features to be effective, a manufacturing authorisation holder who is not himself the original manufacturer of the medicinal product should only be permitted to remove, replace or cover those safety features under strict conditions. In particular, the safety features should be replaced in the case of repackaging by equivalent safety features. To this end, the meaning of the term 'equivalent' should be clearly specified. Those strict conditions should provide adequate safeguards against falsified medicinal products entering the supply chain, in order to protect patients as well as the interests of marketing authorisation holders and manufacturers.

- (13) Manufacturing authorisation holders who repackage medicinal products should be liable for damages in the cases and under the conditions set out in Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products⁽²⁾.
- (14) In order to increase reliability in the supply chain, wholesale distributors should verify that their supplying wholesale distributors are holders of a wholesale distribution authorisation.
- (15) The provisions applicable to the export of medicinal products from the Union and those applicable to the introduction of medicinal products into the Union with the sole purpose of exporting them need to be clarified. Under Directive 2001/83/EC a person exporting medicinal products is a wholesale distributor. The provisions applicable to wholesale distributors as well as good distribution practices should apply to all those activities whenever they are performed on Union territory, including in areas such as free trade zones or free warehouses.
- (16) In order to ensure transparency, a list of wholesale distributors for whom it has been established that they comply with applicable Union legislation by means of an inspection by a competent authority of a Member State, should be published in a database that should be established at Union level.
- (17) The provisions on inspections and controls of all actors involved in the manufacturing and supply of medicinal products and their ingredients should be clarified and specific provisions should apply to different types of actors. This should not prevent Member States from performing additional inspections, where considered appropriate.
- (18) In order to ensure a similar level of protection of human health throughout the Union, and to avoid distortions in the internal market, the harmonised principles and guidelines for inspections of manufacturers and wholesale distributors of medicinal products as well

⁽¹⁾ OJ L 281, 23.11.1995, p. 31.

⁽²⁾ OJ L 210, 7.8.1985, p. 29.

- as of active substances should be strengthened. Such harmonised principles and guidelines should also help to ensure the functioning of existing mutual recognition agreements with third countries whose application depends on efficient and comparable inspection and enforcement throughout the Union.
- (19) Manufacturing plants of active substances should be subject not only to inspections carried out on the grounds of suspected non-compliance but also on the basis of a risk-analysis.
- (20) The manufacture of active substances should be subject to good manufacturing practice regardless of whether those active substances are manufactured in the Union or imported. With regard to the manufacture of active substances in third countries, it should be ensured that the legislative provisions applicable to the manufacturing of active substances intended for export to the Union, as well as inspections of facilities and enforcement of the applicable provisions, provide for a level of protection of public health equivalent to that provided for by Union law.
- (21) The illegal sale of medicinal products to the public via the Internet is an important threat to public health as falsified medicinal products may reach the public in this way. It is necessary to address this threat. In doing so, account should be taken of the fact that specific conditions for retail supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the Treaty on the Functioning of the European Union (TFEU).
- (22) When examining the compatibility with Union law of the conditions for the retail supply of medicinal products, the Court of Justice of the European Union (the Court of Justice) has recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the TFEU and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States must be allowed discretion⁽¹⁾ as regards the conditions for the supply on their territory of medicinal products to the public.
- (23) In particular, in the light of the risks to public health and given the power accorded to Member States to determine the level of protection of public health, the case-law of the Court of Justice has recognised that Member States may, in principle, restrict the retail sale of medicinal products to pharmacists alone⁽²⁾.
- (24) Therefore, and in the light of the case-law of the Court of Justice, Member States should be able to impose conditions justified by the protection of public health upon the retail supply of medicinal products offered for sale at a distance by means of information society services. Such conditions should not unduly restrict the functioning of the internal market.
- (25) The public should be assisted in identifying websites which are legally offering medicinal products for sale at a distance to the public. A common logo should be established, which is recognisable throughout the Union, while allowing for the identification of the Member State where the person offering medicinal products for sale at a distance is established. The Commission should develop the design for such a logo. Websites offering medicinal products for sale at a distance to the public should be linked to the website of the competent authority concerned. The websites of the competent authorities of Member States, as well as that of the European Medicines Agency (the Agency), should give an explanation of the use of the logo. All those websites should be linked in order to provide comprehensive information to the public.
- (26) In addition, the Commission should, in cooperation with the Agency and Member States, run awareness campaigns to warn of the risks of purchasing medicinal products from illegal sources via the Internet.
- (27) Member States should impose effective penalties for acts involving falsified medicinal products taking into account the threat to public health posed by those products.
- (28) The falsification of medicinal products is a global problem, requiring effective and enhanced international coordination and cooperation in order to ensure that anti-falsification strategies are more effective, in particular as regards sale of such products via the Internet. To that end, the Commission and the Member States should cooperate closely and support ongoing work in international fora on this subject, such as the Council of Europe, Europol and the United Nations. In addition, the Commission, working closely with Member States, should cooperate with the competent authorities of third countries with a view to effectively combating the trade in falsified medicinal products at a global level.
- (29) This Directive is without prejudice to provisions concerning intellectual property rights. It aims specifically to prevent falsified medicinal products from entering the legal supply chain.
- (30) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to supplement the provisions of Directive 2001/83/EC, as amended by this Directive, concerning good manufacturing and distribution practices for active substances, concerning detailed rules for medicinal products introduced into the Union without being imported and concerning safety features. It is of particular importance that the Commission carry

⁽¹⁾ Judgment of the Court of 19 May 2009 in Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others v Saarland* ECR [2009] I-4171, paragraphs 19 and 31.

⁽²⁾ Judgment of the Court of 19 May 2009 in Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others v Saarland* ECR [2009] I-4171, paragraphs 34 and 35.

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 Council.

(31) In order to ensure uniform conditions for implementation, implementing powers should be conferred on the Commission as regards the adoption of measures for the assessment of the regulatory framework applicable to the manufacturing of active substances exported from third countries to the Union and as regards a common logo that identifies websites which are legally offering medicinal products for sale at a distance to the public. Those powers should be exercised in accordance with 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⁽¹⁾.

(32) The safety features for medicinal products introduced under this Directive require substantial adaptations to manufacturing processes. In order to enable manufacturers to make those adaptations, the time limits for the application of the provisions on the safety features should be sufficiently long and should be calculated as from the date of publication in the *Official Journal of the European Union* of the delegated acts setting out detailed rules in relation to those safety features. It should also be taken into account that some Member States already have a national system in place. Those Member States should be granted an additional transitional period for adapting to the harmonised Union system.

(33) Since the objective of this Directive, namely to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicinal products, cannot be sufficiently achieved by the Member States, and can, by reason of the scale of the measure, 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.

(34) It is important that the competent authorities of the Member States, the Commission and the Agency cooperate to ensure the exchange of information on measures taken to combat the falsification of medicinal products and on the penalties systems that are in place. Currently, such exchange takes place through the Working Group of Enforcement Officers. Member States should ensure that patients' and consumers' organisations are kept informed about enforcement activities to the extent that this is compatible with operational needs.

(35) In accordance with point 34 of the Interinstitutional Agreement on better law-making⁽²⁾, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(36) Directive 2001/83/EC was recently amended by Directive 2010/84/EU⁽³⁾ as regards pharmacovigilance. That Directive, inter alia, amended Article 111 with regard to inspections and Article 116 with regard to the suspension and revocation and variation of marketing authorisations under certain circumstances. Furthermore, it inserted provisions on delegated acts in Articles 121a, 121b and 121c of Directive 2001/83/EC. This Directive requires some further and complementary changes to those Articles of Directive 2001/83/EC.

(37) Directive 2001/83/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/83/EC is hereby amended as follows:

(1) Article 1 is amended as follows:

(a) the following points are inserted:

'3a. Active substance:

Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

3b. Excipient:

Any constituent of a medicinal product other than the active substance and the packaging material.;

(b) the following point is inserted:

'17a. Brokering of medicinal products:

All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.;

(c) the following point is added:

'33. Falsified medicinal product:

⁽¹⁾ OJ L 55, 28.2.2011, p. 13.

⁽²⁾ OJ C 321, 31.12.2003, p. 1.

⁽³⁾ OJ L 348, 31.12.2010, p. 74.

Any medicinal product with a false representation of:

- (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
- (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
- (c) its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.;

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

‘3. Notwithstanding paragraph 1 of this Article and Article 3(4), Title IV of this Directive shall apply to the manufacture of medicinal products intended only for export and to intermediate products, active substances and excipients.

4. Paragraph 1 shall be without prejudice to Articles 52b and 85a.;

(3) in Article 8(3), the following point is inserted:

‘(ha) A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with principles and guidelines of good manufacturing practice by conducting audits, in accordance with point (f) of Article 46. The written confirmation shall contain a reference to the date of the audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice.;

(4) in Article 40, paragraph 4 is replaced by the following:

‘4. Member States shall enter the information relating to the authorisation referred to in paragraph 1 of this Article in the Union database referred to in Article 111(6).;

(5) in Article 46, point (f) is replaced by the following:

‘(f) to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use only active substances, which have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances. To this end, the holder of the manufacturing authorisation shall verify compliance by the manufacturer and distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. The

holder of the manufacturing authorisation shall verify such compliance either by himself or, without prejudice to his responsibility as provided for in this Directive, through an entity acting on his behalf under a contract.

The holder of the manufacturing authorisation shall ensure that the excipients are suitable for use in medicinal products by ascertaining what the appropriate good manufacturing practice is. This shall be ascertained on the basis of a formalised risk assessment in accordance with the applicable guidelines referred to in the fifth paragraph of Article 47. Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects. The holder of the manufacturing authorisation shall ensure that the appropriate good manufacturing practice so ascertained, is applied. The holder of the manufacturing authorisation shall document the measures taken under this paragraph;

(g) to inform the competent authority and the marketing authorisation holder immediately if he obtains information that medicinal products which come under the scope of his manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale by means of information society services;

(h) to verify that the manufacturers, importers or distributors from whom he obtains active substances are registered with the competent authority of the Member State in which they are established;

(i) to verify the authenticity and quality of the active substances and the excipients.;

(6) the following Article is inserted:

‘Article 46b

1. Member States shall take appropriate measures to ensure that the manufacture, import and distribution on their territory of active substances, including active substances that are intended for export, comply with good manufacturing practice and good distribution practices for active substances.

2. Active substances shall only be imported if the following conditions are fulfilled:

(a) the active substances have been manufactured in accordance with standards of good manufacturing practice at least equivalent to those laid down by the Union pursuant to the third paragraph of Article 47; and

(b) the active substances are accompanied by a written confirmation from the competent authority of the exporting third country of the following:

- (i) the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Union pursuant to the third paragraph of Article 47;
- (ii) the manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and
- (iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the Union without any delay.

This written confirmation shall be without prejudice to the obligations set out in Article 8 and in point (f) of Article 46.

3. The requirement set out in point (b) of paragraph 2 of this Article shall not apply if the exporting country is included in the list referred to in Article 111b.

4. Exceptionally and where necessary to ensure the availability of medicinal products, when a plant manufacturing an active substance for export has been inspected by a Member State and was found to comply with the principles and guidelines of good manufacturing practice laid down pursuant to the third paragraph of Article 47, the requirement set out in point (b) of paragraph 2 of this Article may be waived by any Member State for a period not exceeding the validity of the certificate of Good Manufacturing Practice. Member States that make use of the possibility of such waiver, shall communicate this to the Commission.;

- (7) in Article 47, the third and fourth paragraphs are replaced by the following:

'The Commission shall adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions laid down in Articles 121b and 121c, the principles and guidelines of good manufacturing practice for active substances referred to in the first paragraph of point (f) of Article 46 and in Article 46b.

The principles of good distribution practices for active substances referred to in the first paragraph of point (f) of Article 46 shall be adopted by the Commission in the form of guidelines.

The Commission shall adopt guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients referred to in the second paragraph of point (f) of Article 46.;

- (8) the following Article is inserted:

'Article 47a

1. The safety features referred to in point (o) of Article 54 shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:

- (a) the manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;
- (b) the manufacturing authorisation holder complies with point (o) of Article 54 by replacing those safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging as defined in point 23 of Article 1.

Safety features shall be considered equivalent if they:

- (i) comply with the requirements set out in the delegated acts adopted pursuant to Article 54a(2); and
- (ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;
- (c) the replacement of the safety features is conducted in accordance with applicable good manufacturing practice for medicinal products; and
- (d) the replacement of the safety features is subject to supervision by the competent authority.

2. Manufacturing authorisation holders, including those performing the activities referred to in paragraph 1 of this Article, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Directive 85/374/EEC.;

- (9) in Article 51(1), the following subparagraph is inserted before the second subparagraph:

'The qualified person referred to in Article 48 shall in the case of medicinal products intended to be placed on the market in the Union, ensure that the safety features referred to in point (o) of Article 54 have been affixed on the packaging.;

- (10) the following Articles are inserted:

'Article 52a

1. Importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent authority of the Member State in which they are established.

2. The registration form shall include, at least, the following information:

- (i) name or corporate name and permanent address;
- (ii) the active substances which are to be imported, manufactured or distributed;
- (iii) particulars regarding the premises and the technical equipment for their activity.

3. The persons referred to in paragraph 1 shall submit the registration form to the competent authority at least 60 days prior to the intended commencement of their activity.

4. The competent authority may, based on a risk assessment, decide to carry out an inspection. If the competent authority notifies the applicant within 60 days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the competent authority has notified the applicant that he may commence the activity. If within 60 days of the receipt of the registration form the competent authority has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.

5. The persons referred to in paragraph 1 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed must be notified immediately.

6. Persons referred to in paragraph 1 who had commenced their activity before 2 January 2013 shall submit the registration form to the competent authority by 2 March 2013.

7. Member States shall enter the information provided in accordance with paragraph 2 of this Article in the Union database referred to in Article 111(6).

8. This Article shall be without prejudice to Article 111.

Article 52b

1. Notwithstanding Article 2(1), and without prejudice to Title VII, Member States shall take the necessary measures in order to prevent medicinal products that are introduced into the Union, but are not intended to be placed on the market of the Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified.

2. In order to establish what the necessary measures referred to in paragraph 1 of this Article are, the Commission may adopt, by means of delegated acts in accordance with Article 121a, and subject to the conditions laid down in Articles 121b and 121c, measures supplementing paragraph 1 of this Article as regards the criteria to be considered and the verifications to be made when assessing the potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market.;

(11) in Article 54, the following point is added:

'(o) for medicinal products other than radiopharmaceuticals referred to in Article 54a(1), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:

- verify the authenticity of the medicinal product, and
- identify individual packs,

as well as a device allowing verification of whether the outer packaging has been tampered with.;

(12) the following Article is inserted:

'Article 54a

1. Medicinal products subject to prescription shall bear the safety features referred to in point (o) of Article 54, unless they have been listed in accordance with the procedure pursuant to point (b) of paragraph 2 of this Article.

Medicinal products not subject to prescription shall not bear the safety features referred to in point (o) of Article 54, unless, by way of exception, they have been listed in accordance with the procedure pursuant to point (b) of paragraph 2 of this Article, after having been assessed to be at risk of falsification.

2. The Commission shall adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions laid down in Articles 121b and 121c, measures supplementing point (o) of Article 54 with the objective of establishing the detailed rules for the safety features referred to in point (o) of Article 54.

Those delegated acts shall set out:

- (a) the characteristics and technical specifications of the unique identifier of the safety features referred to in point (o) of Article 54 that enables the authenticity of medicinal products to be verified and individual packs to be identified. When establishing the safety features due consideration shall be given to their cost-effectiveness;
- (b) the lists containing the medicinal products or product categories which, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in point (o) of Article 54. Those lists shall be established considering the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products. To this end, at least the following criteria shall be applied:
 - (i) the price and sales volume of the medicinal product;
 - (ii) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date;
 - (iii) the specific characteristics of the medicinal products concerned;
 - (iv) the severity of the conditions intended to be treated;
 - (v) other potential risks to public health;

(c) the procedures for the notification to the Commission provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);

(d) the modalities for the verification of the safety features referred to in point (o) of Article 54 by the manufacturers, wholesalers, pharmacists and persons authorised or entitled to supply medicinal products to the public and by the competent authorities. Those modalities shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in point (o) of Article 54 and determine the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account;

(e) provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in point (o) of Article 54, shall be contained. The costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.

3. When adopting the measures referred to in paragraph 2, the Commission shall take due account of at least the following:

(a) the protection of personal data as provided for in Union law;

(b) the legitimate interests to protect information of a commercially confidential nature;

(c) the ownership and confidentiality of the data generated by the use of the safety features; and

(d) the cost-effectiveness of the measures.

4. The national competent authorities shall notify the Commission of non-prescription medicinal products which they judge to be at risk of falsification and may inform the Commission of medicinal products which they deem not to be at risk according to the criteria set out in point (b) of paragraph 2 of this Article.

5. Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in point (o) of Article 54 to any medicinal product subject to prescription or subject to reimbursement.

Member States may, for the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology, use the information contained in the repositories system referred to in point (e) of paragraph 2 of this Article.

Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering

device referred to in point (o) of Article 54 to any medicinal product.;

(13) in Article 57, the fourth indent of the first paragraph is replaced by the following:

‘— authenticity and identification in accordance with Article 54a(5).’;

(14) the heading of title VII is replaced by the following:

‘Wholesale distribution and brokering of medicinal products’;

(15) in Article 76, paragraph 3 is replaced by the following:

‘3. Any distributor, not being the marketing authorisation holder, who imports a medicinal product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the medicinal product will be imported of his intention to import that product. In the case of medicinal products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the competent authority shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority for examining the notification.

4. In the case of medicinal products which have been granted an authorisation pursuant to Regulation (EC) No 726/2004, the distributor shall submit the notification in accordance with paragraph 3 of this Article to the marketing authorisation holder and the Agency. A fee shall be payable to the Agency for checking that the conditions laid down in Union legislation on medicinal products and in the marketing authorisations are observed.’;

(16) Article 77 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the premises located on their territory for which it is valid.’;

(b) paragraphs 4 and 5 are replaced by the following:

‘4. Member States shall enter the information relating to the authorisations referred to in paragraph 1 of this Article in the Union database referred to in Article 111(6). At the request of the Commission or any Member State, Member States shall provide all appropriate information concerning the individual authorisations which they have granted under paragraph 1 of this Article.

5. Checks on the persons authorised to engage in activity as a wholesaler in medicinal products, and the inspection of their premises, shall be carried out under the responsibility of the Member State which granted the authorisation for premises located on its territory.’;

(17) Article 80 is amended as follows:

(a) the following point is inserted:

‘(ca) they must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts referred to in Article 54a(2);’

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

‘(e) they must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products received, dispatched or brokered at least the following information:

- date,
- name of the medicinal product,
- quantity received, supplied or brokered,
- name and address of the supplier or consignee, as appropriate,
- batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 54;’

(c) the following points are added:

‘(h) they must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;

(i) they must immediately inform the competent authority and, where applicable, the marketing authorisation holder, of medicinal products they receive or are offered which they identify as falsified or suspect to be falsified.’

(d) the following paragraphs are added:

‘For the purposes of point (b), where the medicinal product is obtained from another wholesale distributor, wholesale distribution authorisation holders must verify compliance with the principles and guidelines of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation.

Where the medicinal product is obtained from the manufacturer or importer, wholesale distribution authorisation holders must verify that the manufacturer or importer holds a manufacturing authorisation.

Where the medicinal product is obtained through brokering, the wholesale distribution authorisation holders must verify that the broker involved fulfils the requirements set out in this Directive.’

(18) in the first paragraph of Article 82, the following indent is added:

‘— batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 54;’

(19) the following Articles are inserted:

‘Article 85a

In the case of wholesale distribution of medicinal products to third countries, Article 76 and point (c) of Article 80 shall not apply. Moreover, points (b) and (ca) of Article 80 shall not apply where a product is directly received from a third country but not imported. The requirements set out in Article 82 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.

Article 85b

1. Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive.

Persons brokering medicinal products shall have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and supervision of their activities by competent authorities.

The requirements set out in points (d) to (i) of Article 80 shall apply *mutatis mutandis* to the brokering of medicinal products.

2. Persons may only broker medicinal products if they are registered with the competent authority of the Member State of their permanent address referred to in paragraph 1. Those persons shall submit, at least, their name, corporate name and permanent address in order to register. They shall notify the competent authority of any changes thereof without unnecessary delay.

Persons brokering medicinal products who had commenced their activity before 2 January 2013 shall register with the competent authority by 2 March 2013.

The competent authority shall enter the information referred to in the first subparagraph in a register that shall be publicly accessible.

3. The guidelines referred to in Article 84 shall include specific provisions for brokering.

4. This Article shall be without prejudice to Article 111. Inspections referred to in Article 111 shall be carried out under the responsibility of the Member State where the person brokering medicinal products is registered.

If a person brokering medicinal products does not comply with the requirements set out in this Article, the competent authority may decide to remove that person from the register referred to in paragraph 2. The competent authority shall notify that person thereof;

(20) the following Title is inserted before Title VIII:

TITLE VIII

SALE AT A DISTANCE TO THE PUBLIC

Article 85c

1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services as defined in 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 (*) under the following conditions:

- (a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;
- (b) the person referred to in point (a) has notified the Member State in which that person is established of at least the following information:
 - (i) name or corporate name and permanent address of the place of activity from where those medicinal products are supplied;
 - (ii) the starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services;
 - (iii) the address of the website used for that purpose and all relevant information necessary to identify that website;
 - (iv) if applicable, the classification in accordance with Title VI of the medicinal products offered for sale at a distance to the public by means of information society services.

Where appropriate, that information shall be updated;

- (c) the medicinal products comply with the national legislation of the Member State of destination in accordance with Article 6(1);
- (d) without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) (**), the website offering the medicinal products contains at least:
 - (i) the contact details of the competent authority or the authority notified pursuant to point (b);

(ii) a hyperlink to the website referred to in paragraph 4 of the Member State of establishment;

(iii) the common logo referred to in paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of medicinal products. The common logo shall contain a hyperlink to the entry of the person in the list referred to in point (c) of paragraph 4.

2. Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.

3. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering medicinal products for sale at a distance to the public is established. That logo shall be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with point (d) of paragraph 1.

In order to harmonise the functioning of the common logo, the Commission shall adopt implementing acts regarding:

- (a) the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo;
- (b) the design of the common logo.

Those implementing acts shall, where necessary, be amended to take account of technical and scientific progress. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 121(2).

4. Each Member State shall set up a website providing at least the following:

- (a) information on the national legislation applicable to the offering of medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member States regarding classification of medicinal products and the conditions for their supply;
- (b) information on the purpose of the common logo;
- (c) the list of persons offering the medicinal products for sale at a distance to the public by means of information society services in accordance with paragraph 1 as well as their website addresses;
- (d) background information on the risks related to medicinal products supplied illegally to the public by means of information society services.

This website shall contain a hyperlink to the website referred to in paragraph 5.

5. The Agency shall set up a website providing the information referred to in points (b) and (d) of paragraph 4, information on the Union legislation applicable to falsified medicinal products as well as hyperlinks to the Member States' websites referred to in paragraph 4. The Agency's website shall explicitly mention that the Member States' websites contain information on persons authorised or entitled to supply medicinal products at a distance to the public by means of information society services in the Member State concerned.

6. Without prejudice to Directive 2000/31/EC and the requirements set out in this Title, Member States shall take the necessary measures to ensure that other persons than those referred to in paragraph 1 that offer medicinal products for sale at a distance to the public by means of information society services and that operate on their territory are subject to effective, proportionate and dissuasive penalties.

Article 85d

Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website.

(*) OJ L 204, 21.7.1998, p. 37.

(**) OJ L 178, 17.7.2000, p. 1.;

(21) Article 111 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The competent authority of the Member State concerned shall, in cooperation with the Agency, ensure that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced, and, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to carry out tests on samples. This cooperation shall consist in sharing information with the Agency on both inspections that are planned and that have been conducted. Member States and the Agency shall cooperate in the coordination of inspections in third countries. The inspections shall include but not be limited to the ones mentioned in paragraphs 1a to 1f.

1a. Manufacturers, located in the Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections.

1b. The competent authority of the Member State concerned shall have a system of supervision including

by inspections at an appropriate frequency based on risk, at the premises of the manufacturers, importers, or distributors of active substances, located on its territory, and effective follow-up thereof.

Whenever it considers that there are grounds for suspecting non-compliance with the legal requirements laid down in this Directive, including the principles and guidelines of good manufacturing practice and good distribution practices referred to in point (f) of Article 46 and in Article 47, the competent authority may carry out inspections at the premises of:

(a) manufacturers or distributors of active substances located in third countries;

(b) manufacturers or importers of excipients.

1c. Inspections referred to in paragraphs 1a and 1b may also be carried out in the Union and in third countries at the request of a Member State, the Commission or the Agency.

1d. Inspections may also take place at the premises of marketing authorisation holders and of brokers of medicinal products.

1e. In order to verify whether the data submitted in order to obtain a conformity certificate comply with the monographs of the European Pharmacopoeia, the standardisation body of the nomenclatures and the quality norms within the meaning of the Convention relating to the elaboration of the European Pharmacopoeia (the European Directorate for the Quality of Medicines and Healthcare) may ask the Commission or the Agency to request such an inspection when the starting material concerned is the subject of a European Pharmacopoeia monograph.

1f. The competent authority of the Member State concerned may carry out inspections of starting material manufacturers at the specific request of the manufacturer.

1g. Inspections shall be carried out by officials representing the competent authority who shall be empowered to:

(a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or of excipients, and any laboratories employed by the holder of the manufacturing authorisation to carry out checks pursuant to Article 20;

(b) take samples including with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory designated for that purpose by a Member State;

(c) examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States on 21 May 1975 placing restrictions on these powers with regard to the description of the manufacturing method;

(d) inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any firms employed by the marketing authorisation holder to perform the activities described in Title IX.

1h. Inspections shall be carried out in accordance with the guidelines referred to in Article 111a.;

(b) paragraphs 3 to 6 are replaced by the following:

'3. After every inspection as referred to in paragraph 1, the competent authority shall report on whether the inspected entity complies with the principles and guidelines of good manufacturing practice and good distribution practices referred to in Articles 47 and 84, as applicable, or on whether the marketing authorisation holder complies with the requirements laid down in Title IX.

The competent authority which carried out the inspection shall communicate the content of those reports to the inspected entity.

Before adopting the report, the competent authority shall give the inspected entity concerned the opportunity to submit comments.

4. Without prejudice to any arrangements which may have been concluded between the Union and third countries, a Member State, the Commission or the Agency may require a manufacturer established in a third country to submit to an inspection as referred to in this Article.

5. Within 90 days of an inspection as referred to in paragraph 1, a certificate of good manufacturing practice or good distribution practices shall, when applicable, be issued to the inspected entity if the outcome of the inspection shows that it complies with the principles and guidelines of good manufacturing practice or good distribution practices as provided for by Union legislation.

If inspections are performed as part of the certification procedure for the monographs of the European Pharmacopoeia, a certificate shall be drawn up.

6. Member States shall enter the certificates of good manufacturing practice and good distribution practices which they issue in a Union database managed by the Agency on behalf of the Union. Pursuant to Article 52a(7), Member States shall also enter information in that database regarding the registration of importers, manufacturers and distributors of active substances. The database shall be publicly accessible.;

(c) paragraph 7 is amended as follows:

(i) the words 'paragraph 1' are replaced by the words 'paragraph 1g';

(ii) the words 'used as starting materials' are deleted;

(d) in the first subparagraph of paragraph 8, the words 'paragraph 1(d)' are replaced by the words 'point (d) of paragraph 1g';

(22) the following Articles are inserted:

'Article 111a

The Commission shall adopt detailed guidelines laying down the principles applicable to inspections referred to in Article 111.

Member States shall, in cooperation with the Agency, establish the form and content of the authorisation referred to in Articles 40(1) and 77(1), of the reports referred to in Article 111(3), of the certificates of good manufacturing practice and of the certificates of good distribution practices referred to in Article 111(5).

Article 111b

1. At the request of a third country, the Commission shall assess whether that country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union. If the assessment confirms such equivalence, the Commission shall adopt a decision to include the third country in a list. The assessment shall take the form of a review of relevant documentation and, unless arrangements as referred to in Article 51(2) of this Directive are in place that cover this area of activity, that assessment shall include an on-site review of the third country's regulatory system and, if necessary, an observed inspection of one or more of the third country's manufacturing sites for active substances. In the assessment particular account shall be taken of:

(a) the country's rules for good manufacturing practice;

(b) the regularity of inspections to verify compliance with good manufacturing practice;

(c) the effectiveness of enforcement of good manufacturing practice;

(d) the regularity and rapidity of information provided by the third country relating to non-compliant producers of active substances.

2. The Commission shall adopt the necessary implementing acts to apply the requirements set out in points (a) to (d) of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 121(2).

3. The Commission shall verify regularly whether the conditions laid down in paragraph 1 are fulfilled. The first verification shall take place no later than 3 years after the country has been included in the list referred to in paragraph 1.

4. The Commission shall perform the assessment and verification referred to in paragraphs 1 and 3 in cooperation with the Agency and the competent authorities of the Member States.;

(23) in Article 116, the following paragraph is added:

'The second paragraph of this Article also applies in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to point (d) of Article 8(3), or where controls are not carried out in compliance with the control methods described pursuant to point (h) of Article 8(3).;

(24) the following Article is inserted:

'Article 117a

1. Member States shall have a system in place which aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.

2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.

3. If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which that product was first identified shall, without any delay, transmit a rapid alert notification to all Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

4. Member States shall by 22 July 2013 notify the Commission of the details of their respective national systems referred to in this Article.;

(25) the following Articles are inserted:

'Article 118a

1. The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all necessary measures to ensure that those penalties are implemented. The penalties must be effective, proportionate and dissuasive.

Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.

2. The rules referred to in paragraph 1 shall address, inter alia, the following:

- (a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as the sale of falsified medicinal products at a distance to the public by means of information society services;
- (b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;
- (c) non-compliance with the provisions laid down in this Directive on the use of excipients.

Where relevant, the penalties shall take into account the risk to public health presented by the falsification of medicinal products.

3. The Member States shall notify the national provisions adopted pursuant to this Article to the Commission by 2 January 2013 and shall notify any subsequent amendment of those provisions without delay.

By 2 January 2018, the Commission shall submit a report to the European Parliament and to the Council giving an overview of the transposition measures of Member States as regards this Article, together with an evaluation of the effectiveness of those measures.

Article 118b

Member States shall organise meetings involving patients "and consumers" organisations and, as necessary, Member States' enforcement officers, in order to communicate public information about the actions undertaken in the area of prevention and enforcement to combat the falsification of medicinal products.

Article 118c

Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.;

(26) in Article 121a(1), the words 'Article 22b' are replaced by the words 'Articles 22b, 47, 52b and 54a';

(27) in Article 121b(1), the words 'Article 22b' are replaced by the words 'Articles 22b, 47, 52b and 54a';

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 2 January 2013. They shall forthwith inform the Commission thereof.

2. Member States shall apply those measures from 2 January 2013.

However, the Member States shall apply:

- (a) the provisions necessary to comply with point 6 of Article 1 of this Directive in so far as it relates to Article 46b(2)(b) and Article 46b(3) and (4) of Directive 2001/83/EC as inserted by this Directive from 2 July 2013;
- (b) the provisions necessary to comply with points 8, 9, 11 and 12 of Article 1 of this Directive from 3 years after the date of publication of the delegated acts referred to in point 12 of Article 1 of this Directive.

Nevertheless, Member States which, on 21 July 2011, have systems in place for the purpose referred to in point 11 of Article 1 of this Directive shall apply the provisions necessary to comply with points 8, 9, 11 and 12 of Article 1 of this Directive at the latest from 6 years after the date of application of the delegated acts referred to in point 12 of Article 1 of this Directive;

- (c) the provisions necessary to comply with point 20 of Article 1 of this Directive in so far as it relates to Article 85c of Directive 2001/83/EC as inserted by this Directive at the latest from 1 year after the date of publication of the implementing acts referred to in Article 85c(3) as inserted by this Directive.

3. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such references shall be laid down by Member States.

4. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

At the latest 5 years after the date of application of the delegated acts referred to in Article 54a(2) of Directive 2001/83/EC as inserted by this Directive, the Commission shall submit a report to the European Parliament and to the Council containing the following:

- (a) a description, where possible including quantitative data, of the trends in the falsification of medicinal products in terms of: categories of medicinal products affected, distribution channels including sale at a distance to the public by means of information society services, the Member States concerned, the nature of the falsifications, and the regions of provenance of these products; and

- (b) an evaluation of the contribution of the measures provided for in this Directive regarding the prevention of the entry of falsified medicinal products in the legal supply chain. That evaluation shall in particular assess point (o) of Article 54 and Article 54a of Directive 2001/83/EC as inserted by this Directive.

Article 4

In order to adopt the delegated acts referred to in Article 54a(2) of Directive 2001/83/EC as inserted by this Directive, the Commission shall perform a study assessing at least the following aspects:

- (a) the technical options for the unique identifier of the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC as inserted by this Directive;
- (b) the options for the extent and the modalities of verification of the authenticity of the medicinal product bearing the safety features. This assessment shall take into account the particular characteristics of the supply chains in the Member States;
- (c) the technical options for establishing and managing the repositories system, referred to in point (e) of Article 54a(2) of Directive 2001/83/EC as inserted by this Directive.

The study shall, for each of the options, assess benefits, costs and cost-effectiveness.

Article 5

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

Article 6

This Directive is addressed to the Member States.

Done at Strasbourg, 8 June 2011.

For the European Parliament

The President

J. BUZEK

For the Council

The President

GYŐRI E.

DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011

on the restriction of the use of certain hazardous substances in electrical and electronic equipment

(recast)

(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,

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

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

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

(1) A number of substantial changes are to be made to Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁽⁴⁾. In the interest of clarity, that Directive should be recast.

(2) The disparities between the laws or administrative measures adopted by the Member States regarding the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) could create barriers to trade and distort competition in the Union and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to lay down rules in this field and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste EEE.

(3) Directive 2002/95/EC provides that the Commission shall review the provisions of that Directive, in particular, in order to include in its scope equipment which falls within certain categories and to study the need to adapt the list of restricted substances on the basis of scientific progress, taking into account the precautionary principle, as endorsed by Council Resolution of 4 December 2000.

(4) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste ⁽⁵⁾ gives first priority to prevention in waste legislation. Prevention is defined, inter alia, as measures that reduce the content of harmful substances in materials and products.

(5) Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium ⁽⁶⁾ invited the Commission to pursue without delay the development of specific measures for such a programme. Human health also has to be protected and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should therefore be implemented. The Resolution stresses that the use of cadmium should be limited to cases where suitable alternatives do not exist.

(6) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants ⁽⁷⁾ recalls that the objective of protecting the environment and human health from persistent organic pollutants cannot be sufficiently achieved by the Member States, owing to the trans-boundary effects of those pollutants, and can therefore be better achieved at Union level. Pursuant to that Regulation, releases of persistent organic pollutants, such as dioxins and furans, which are unintentional by-products of industrial processes, should be identified and reduced as soon as possible with the ultimate aim of elimination, where feasible.

(7) The available evidence indicates that measures on the collection, treatment, recycling and disposal of waste EEE as set out in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) ⁽⁸⁾ are necessary to reduce the waste management problems associated with the heavy metals and flame retardants concerned. In spite of those measures, however, significant parts of waste EEE will continue to be found in the current disposal routes inside or outside the Union. Even if waste EEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) would be likely to pose risks to health or the environment, especially when treated in less than optimal conditions.

⁽¹⁾ OJ C 306, 16.12.2009, p. 36.

⁽²⁾ OJ C 141, 29.5.2010, p. 55.

⁽³⁾ Position of the European Parliament of 24 November 2010 (not yet published in the Official Journal) and decision of the Council of 27 May 2011.

⁽⁴⁾ OJ L 37, 13.2.2003, p. 19.

⁽⁵⁾ OJ L 312, 22.11.2008, p. 3.

⁽⁶⁾ OJ C 30, 4.2.1988, p. 1.

⁽⁷⁾ OJ L 158, 30.4.2004, p. 7.

⁽⁸⁾ OJ L 37, 13.2.2003, p. 24.

- (8) Taking into account technical and economic feasibility, including for small and medium sized enterprises (SMEs), the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials. Restricting the use of those hazardous substances is likely to enhance the possibilities and economic profitability of recycling of waste EEE and decrease the negative impact on the health of workers in recycling plants.
- (9) The substances covered by this Directive are scientifically well researched and evaluated and have been subject to different measures both at Union and at national level.
- (10) The measures provided for in this Directive should take into account existing international guidelines and recommendations and should be based on an assessment of available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human health and the environment, with due respect for the precautionary principle, and having regard to the risks which the absence of measures would be likely to create in the Union. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information. The annexes to this Directive should be reviewed periodically to take into account, inter alia, Annexes XIV and XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency⁽¹⁾. In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority. With a view to further restrictions of substances, the Commission should re-investigate the substances that were subject to previous assessments, in accordance with the new criteria set out in this Directive as part of the first review.
- (11) This Directive supplements the general Union waste management legislation, such as Directive 2008/98/EC and Regulation (EC) No 1907/2006.
- (12) A number of definitions should be included in this Directive in order to specify its scope. In addition, the definition of 'electrical and electronic equipment' should be complemented by a definition of 'dependent', to cover the multipurpose character of certain products, where the intended functions of EEE are to be determined on the basis of objective characteristics, such as the design of the product and its marketing.
- (13) Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products⁽²⁾ enables specific ecodesign requirements to be set for energy-related products which may also be covered by this Directive. Directive 2009/125/EC and the implementing measures adopted pursuant to it are without prejudice to Union waste management legislation.
- (14) This Directive should apply without prejudice to Union legislation on safety and health requirements and specific Union waste management legislation, in particular Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators⁽³⁾ and Regulation (EC) No 850/2004.
- (15) The technical development of EEE without heavy metals, PBDE and PBB should be taken into account.
- (16) As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined. To this end, the review and amendment of the list of restricted substances in Annex II should be coherent, maximise synergies with, and reflect the complementary nature of the work carried out under other Union legislation, and in particular under Regulation (EC) No 1907/2006 while ensuring the mutually independent operation of this Directive and that Regulation. Consultation with the relevant stakeholders should be carried out and specific account should be taken of the potential impact on SMEs.
- (17) The development of renewable forms of energy is one of the Union's key objectives, and the contribution made by renewable energy sources to environmental and climate objectives is crucial. Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources⁽⁴⁾ recalls that there should be coherence between those objectives and other Union environmental legislation. Consequently, this Directive should not prevent the development of renewable energy technologies that have no negative impact on health and the environment and that are sustainable and economically viable.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ OJ L 285, 31.10.2009, p. 10.

⁽³⁾ OJ L 266, 26.9.2006, p. 1.

⁽⁴⁾ OJ L 140, 5.6.2009, p. 16.

- (18) Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs or if the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the environmental, health and consumer safety benefits of the substitution or the reliability of substitutes is not ensured. The decision on exemptions and on the duration of possible exemptions should take into account the availability of substitutes and the socioeconomic impact of substitution. Life-cycle thinking on the overall impacts of exemptions should apply, where relevant. Substitution of the hazardous substances in EEE should also be carried out in such a way as to be compatible with the health and safety of users of EEE. The placing on the market of medical devices requires a conformity assessment procedure, according to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽¹⁾ and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices ⁽²⁾, which could require the involvement of a notified body designated by competent authorities of Member States. If such a notified body certifies that the safety of the potential substitute for the intended use in medical devices or in vitro diagnostic medical devices is not demonstrated, the use of that potential substitute will be deemed to have clear negative socioeconomic, health and consumer safety impacts. It should be possible, from the date of entry into force of this Directive, to apply for exemptions for equipment, even before the actual inclusion of that equipment in the scope of this Directive.
- (19) Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, given that the use of those substances in such applications should become avoidable.
- (20) As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available.
- (21) Procedures for assessing the conformity of EEE subject to this Directive should be consistent with relevant Union legislation, in particular 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 ⁽³⁾. Harmonising conformity assessment procedures should give manufacturers legal certainty as to what they have to provide as proof of compliance to the authorities throughout the Union.
- (22) The conformity marking applicable for products at Union level, CE marking, should also apply to EEE that is subject to this Directive.
- (23) The market surveillance mechanisms laid down by 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 ⁽⁴⁾ provide the safeguard mechanisms to check compliance with this Directive.
- (24) In order to ensure uniform conditions for the implementation of this Directive, particularly with regard to the guidelines and format of applications for exemptions, 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 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 ⁽⁵⁾.
- (25) For the purposes of achieving the objectives of this Directive the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of amendments to Annex II, detailed rules for complying with maximum concentration values, and the adaptation of Annexes III and IV to technical and scientific progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (26) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (27) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive set out in Annex VII, Part B.
- (28) When reviewing this Directive, a thorough analysis of its coherence with Regulation (EC) No 1907/2006 should be carried out by the Commission.
- (29) In accordance with paragraph 34 of the Interinstitutional Agreement on better law-making ⁽⁶⁾, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and their transposition measures, and to make those tables public.

⁽¹⁾ OJ L 169, 12.7.1993, p. 1.

⁽²⁾ OJ L 331, 7.12.1998, p. 1.

⁽³⁾ OJ L 218, 13.8.2008, p. 82.

⁽⁴⁾ OJ L 218, 13.8.2008, p. 30.

⁽⁵⁾ OJ L 55, 28.2.2011, p. 13.

⁽⁶⁾ OJ C 321, 31.12.2003, p. 1.

(30) Since the objective of this Directive, namely to establish restrictions on the use of hazardous substances in EEE, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the problem and its implications in respect of other Union legislation on recovery and disposal of waste and areas of common interest, such as human health protection, 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,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Subject matter

This Directive lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.

Article 2

Scope

1. This Directive shall, subject to paragraph 2, apply to EEE falling within the categories set out in Annex I.

2. Without prejudice to Article 4(3) and 4(4), Member States shall provide that EEE that was outside the scope of Directive 2002/95/EC, but which would not comply with this Directive, may nevertheless continue to be made available on the market until 22 July 2019.

3. This Directive shall apply without prejudice to the requirements of Union legislation on safety and health, and on chemicals, in particular Regulation (EC) No 1907/2006, as well as the requirements of specific Union waste management legislation.

4. This Directive does not apply to:

- (a) equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;
- (b) equipment designed to be sent into space;
- (c) equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
- (d) large-scale stationary industrial tools;
- (e) large-scale fixed installations;

- (f) means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
- (g) non-road mobile machinery made available exclusively for professional use;
- (h) active implantable medical devices;
- (i) photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
- (j) equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

Article 3

Definitions

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

- (1) 'electrical and electronic equipment' or 'EEE' means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;
- (2) for the purposes of point 1, 'dependent' means, with regard to EEE, needing electric currents or electromagnetic fields to fulfil at least one intended function;
- (3) 'large-scale stationary industrial tools' means a large-scale assembly of machines, equipment, and/or components, functioning together for a specific application, permanently installed and de-installed by professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility;
- (4) 'large-scale fixed installation' means a large-scale combination of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, intended to be used permanently in a pre-defined and dedicated location, and de-installed by professionals;
- (5) 'cables' means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other;
- (6) 'manufacturer' means any natural or legal person who manufactures an EEE or who has an EEE designed or manufactured and markets it under his name or trademark;
- (7) '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;

- (8) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an EEE available on the market;
- (9) 'importer' means any natural or legal person established within the Union, who places an EEE from a third country on the Union market;
- (10) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (11) 'making available on the market' means any supply of an EEE 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;
- (12) 'placing on the market' means making available an EEE on the Union market for the first time;
- (13) 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to 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⁽¹⁾ on the basis of a request made by the Commission in accordance with Article 6 of Directive 98/34/EC;
- (14) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, process or service;
- (15) 'CE marking' means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (16) 'conformity assessment' means the process demonstrating whether the requirements of this Directive relating to an EEE, are met;
- (17) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that EEE complies with the requirements set out in this Directive and does not endanger health, safety or other issues of public interest protection;
- (18) 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;
- (19) 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;
- (20) 'homogeneous material' means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes;
- (21) 'medical device' means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EEC and which is also EEE;
- (22) 'in vitro diagnostic medical device' means an in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC;
- (23) 'active implantable medical device' means any active implantable medical device within the meaning of point (c) of Article 1(2) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices⁽²⁾;
- (24) 'industrial monitoring and control instruments' means monitoring and control instruments designed for exclusively industrial or professional use;
- (25) 'availability of a substitute' means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II;
- (26) 'reliability of a substitute' means the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time;
- (27) 'spare part' means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part;
- (28) 'non-road mobile machinery made available exclusively for professional use' means machinery, with an on-board power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and is made available exclusively for professional use.

Article 4

Prevention

1. Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II.

2. For the purposes of this Directive, no more than the maximum concentration value by weight in homogeneous materials as specified in Annex II shall be tolerated. The Commission shall adopt, by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, detailed rules for complying with these maximum concentration values taking into account, inter alia, surface coatings.

⁽¹⁾ OJ L 204, 21.7.1998, p. 37.

⁽²⁾ OJ L 189, 20.7.1990, p. 17.

3. Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016 and to industrial monitoring and control instruments which are placed on the market from 22 July 2017.

4. Paragraph 1 shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:

- (a) EEE placed on the market before 1 July 2006;
- (b) medical devices placed on the market before 22 July 2014;
- (c) in vitro diagnostic medical devices placed on the market before 22 July 2016;
- (d) monitoring and control instruments placed on the market before 22 July 2014;
- (e) industrial monitoring and control instruments placed on the market before 22 July 2017;
- (f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

5. Paragraph 1 shall not apply to reused spare parts, recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.

6. Paragraph 1 shall not apply to the applications listed in Annexes III and IV.

Article 5

Adaptation of the Annexes to scientific and technical progress

1. For the purposes of adapting Annexes III and IV to scientific and technical progress, and in order to achieve the objectives set out in Article 1, the Commission shall adopt by means of individual delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, the following measures:

- (a) inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 and where any of the following conditions is fulfilled:
 - their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable,
 - the reliability of substitutes is not ensured,
 - the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution. Decisions on the duration of any exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant;

- (b) deletion of materials and components of EEE from the lists in Annexes III and IV where the conditions set out in point (a) are no longer fulfilled.

2. Measures adopted in accordance with point (a) of paragraph 1 shall, for categories 1 to 7, 10 and 11 of Annex I, have a validity period of up to 5 years and, for categories 8 and 9 of Annex I, a validity period of up to 7 years. The validity periods are to be decided on a case-by-case basis and may be renewed.

For the exemptions listed in Annex III as at 21 July 2011, the maximum validity period, which may be renewed, shall, for categories 1 to 7 and 10 of Annex I, be 5 years from 21 July 2011 and, for categories 8 and 9 of Annex I, 7 years from the relevant dates laid down in Article 4(3), unless a shorter period is specified.

For the exemptions listed in Annex IV as at 21 July 2011, the maximum validity period, which may be renewed, shall be 7 years from the relevant dates laid down in Article 4(3), unless a shorter period is specified.

3. An application for granting, renewing or revoking an exemption shall be made to the Commission in accordance with Annex V.

4. The Commission shall:

- (a) acknowledge receipt of an application in writing within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application;
- (b) inform the Member States of the application without delay and make the application and any supplementary information supplied by the applicant available to them;
- (c) make a summary of the application available to the public;
- (d) evaluate the application and its justification.

5. An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.

The Commission shall decide on an application for renewal of an exemption no later than 6 months before the expiry date of the existing exemption unless specific circumstances justify other deadlines. The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission.

6. In the event that the application for renewal of an exemption is rejected or that an exemption is revoked, the exemption shall expire at the earliest 12 months, and at the latest 18 months, after the date of the decision.

7. Before Annexes are amended, the Commission shall, *inter alia*, consult economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations and make the comments received publicly available.

8. The Commission shall adopt a harmonised format for applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

Article 6

Review and amendment of list of restricted substances in Annex II

1. With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter on its own initiative or following the submission of a proposal by a Member State containing the information referred to in paragraph 2.

The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, *inter alia*, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation.

In order to review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:

- (a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
- (b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;
- (c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;
- (d) could be replaced by substitutes or alternative technologies which have less negative impacts.

During that review, the Commission shall consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.

2. The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:

- (a) precise and clear wording of the proposed restriction;
- (b) references and scientific evidence for the restriction;
- (c) information on the use of the substance or the group of similar substances in EEE;
- (d) information on detrimental effects and exposure in particular during waste EEE management operations;
- (e) information on possible substitutes and other alternatives, their availability and reliability;
- (f) justification for considering a Union-wide restriction as the most appropriate measure;
- (g) socioeconomic assessment.

3. The measures referred to in this Article shall be adopted by the Commission by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22.

Article 7

Obligations of manufacturers

Member States shall ensure that:

- (a) when placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with the requirements set out in Article 4;
- (b) manufacturers draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC or have it carried out;
- (c) where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to in point (b), manufacturers draw up an EU declaration of conformity and affix the CE marking on the finished product. Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up;
- (d) manufacturers keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market;

- (e) manufacturers ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account;
- (f) manufacturers keep a register of non-conforming EEE and product recalls, and keep distributors informed thereof;
- (g) manufacturers ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;
- (h) manufacturers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted. Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply;
- (i) manufacturers who consider or have reason to believe that EEE which they have placed on the market is not in conformity with this Directive immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- (j) manufacturers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.
- keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years following the placing on the market of the EEE,
- 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 an EEE with this Directive,
- cooperate with the competent national authorities, at their request, on any action taken to ensure compliance with this Directive of EEE covered by their mandate.

Article 9

Obligations of importers

Member States shall ensure that:

- (a) importers place only EEE that complies with this Directive on the Union market;
- (b) importers, before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and that they further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in points (f) and (g) of Article 7;
- (c) where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, that importer does not place the EEE on the market until it has been brought into conformity, and that that importer informs the manufacturer and the market surveillance authorities to that effect;
- (d) importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply;
- (e) importers, in order to ensure compliance with this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;
- (f) importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of

Article 8

Obligations of authorised representatives

Member States shall ensure that:

- (a) manufacturers have the possibility to appoint an authorised representative by written mandate. The obligations laid down in point (a) of Article 7 and the drawing up of technical documentation shall not form part of the authorised representative's mandate;
- (b) an authorised representative performs the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

- (g) importers keep, for 10 years following the placing on the market of the EEE, 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;
- (h) importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

Article 10

Obligations of distributors

Member States shall ensure that:

- (a) when making an EEE available on the market, distributors act with due care in relation to the requirements applicable in particular by verifying that the EEE bears the CE marking, that it is accompanied by the required documents in a language which can be easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in points (g) and (h) of Article 7 and in point (d) of Article 9;
- (b) where a distributor considers or has reason to believe that an EEE is not in conformity with Article 4, that distributor does not make the EEE available on the market until it has been brought into conformity, and that that distributor informs the manufacturer or the importer as well as the market surveillance authorities to that effect;
- (c) distributors who consider or have reason to believe that an EEE which they have made available on the market is not in conformity with this Directive make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, are taken and that they immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- (d) distributors, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of EEE with this Directive, and that they cooperate with that authority, at its request, on any action taken to ensure the compliance with this Directive of the EEE which they have made available on the market.

Article 11

Cases in which obligations of manufacturers apply to importers and distributors

Member States shall ensure that an importer or distributor is considered a manufacturer for the purposes of this Directive and that he is subject to the obligations of the manufacturer under Article 7, where he places EEE on the market under his name or trademark or modifies EEE already placed on the market in such a way that compliance with the applicable requirements may be affected.

Article 12

Identification of economic operators

Member States shall ensure that economic operators, on request, identify the following to the market surveillance authorities, for 10 years following the placing on the market of the EEE:

- (a) any economic operator who has supplied them with an EEE;
- (b) any economic operator to whom they have supplied an EEE.

Article 13

EU declaration of conformity

1. The EU declaration of conformity shall state that it has been demonstrated that the requirements specified in Article 4 have been met.
 2. The EU declaration of conformity shall have the model structure and shall contain the elements specified in Annex VI and shall be updated. It shall be translated into the language or languages required by the Member State on the market of which the product is placed or made available.
- Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up.
3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the EEE with this Directive.

Article 14

General principles of the CE marking

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

Article 15

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the finished EEE or to its data plate. Where that is not possible or not warranted on account of the nature of the EEE, it shall be affixed to the packaging and to the accompanying documents.
2. The CE marking shall be affixed before the EEE is placed on the market.

3. Member States shall build upon existing mechanisms to ensure the correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the CE marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

Article 16

Presumption of conformity

1. In the absence of evidence to the contrary, Member States shall presume EEE bearing the CE marking to comply with this Directive.

2. Materials, components and EEE on which tests and measurements demonstrating compliance with the requirements of Article 4 have been performed, or which have been assessed, in accordance with harmonised standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the requirements of this Directive.

Article 17

Formal objection to a harmonised standard

1. Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Article 4, the Commission or the Member State concerned shall bring the matter before the Committee set up pursuant to Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, after consulting the relevant European standardisation bodies, deliver its opinion without delay.

2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

Article 18

Market surveillance and controls of EEE entering the Union market

Member States shall carry out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008.

Article 19

Committee procedure

1. The Commission shall be assisted by the committee set up pursuant to Article 39 of Directive 2008/98/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 5 of Regulation (EU) No 182/2011 shall apply.

Article 20

Exercise of the delegation

1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5 year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.

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

3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22.

Article 21

Revocation of the delegation

1. The delegation of power referred to in Article 4(2), Article 5(1) and Article 6 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 22

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council that period shall be extended by 2 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 23

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 2 January 2013 and shall notify it without delay of any subsequent amendment affecting them.

Article 24

Review

1. No later than 22 July 2014 the Commission shall examine the need to amend the scope of this Directive in respect of the EEE referred to in Article 2, and shall present a report thereon to the European Parliament and the Council accompanied by a legislative proposal, if appropriate, with respect to any additional exclusions related to that EEE.

2. No later than 22 July 2021 the Commission shall carry out a general review of this Directive, and shall present a report to the European Parliament and the Council accompanied, if appropriate, by a legislative proposal.

Article 25

Transposition

1. Member States shall adopt and publish, by 2 January 2013, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a

reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 26

Repeal

Directive 2002/95/EC as amended by the acts listed in Annex VII, Part A is repealed with effect from 3 January 2013 without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directive set out in Annex VII, Part B.

References to the repealed acts shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VIII.

Article 27

Entry into force

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

Article 28

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 8 June 2011.

For the European Parliament
The President
J. BUZEK

For the Council
The President
GYŐRI E.

ANNEX I

Categories of EEE covered by this Directive

1. Large household appliances.
 2. Small household appliances.
 3. IT and telecommunications equipment.
 4. Consumer equipment.
 5. Lighting equipment.
 6. Electrical and electronic tools.
 7. Toys, leisure and sports equipment.
 8. Medical devices.
 9. Monitoring and control instruments including industrial monitoring and control instruments.
 10. Automatic dispensers.
 11. Other EEE not covered by any of the categories above.
-

*ANNEX II***Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials**

Lead (0,1 %)

Mercury (0,1 %)

Cadmium (0,01 %)

Hexavalent chromium (0,1 %)

Polybrominated biphenyls (PBB) (0,1 %)

Polybrominated diphenyl ethers (PBDE) (0,1 %)

ANNEX III

Applications exempted from the restriction in Article 4(1)

Exemption		Scope and dates of applicability
1	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
1(a)	For general lighting purposes < 30 W: 5 mg	Expires on 31 December 2011; 3,5 mg may be used per burner after 31 December 2011 until 31 December 2012; 2,5 mg shall be used per burner after 31 December 2012
1(b)	For general lighting purposes \geq 30 W and < 50 W: 5 mg	Expires on 31 December 2011; 3,5 mg may be used per burner after 31 December 2011
1(c)	For general lighting purposes \geq 50 W and < 150 W: 5 mg	
1(d)	For general lighting purposes \geq 150 W: 15 mg	
1(e)	For general lighting purposes with circular or square structural shape and tube diameter \leq 17 mm	No limitation of use until 31 December 2011; 7 mg may be used per burner after 31 December 2011
1(f)	For special purposes: 5 mg	
2(a)	Mercury in double-capped linear fluorescent lamps for general lighting purposes not exceeding (per lamp):	
2(a)(1)	Tri-band phosphor with normal lifetime and a tube diameter < 9 mm (e.g. T2): 5 mg	Expires on 31 December 2011; 4 mg may be used per lamp after 31 December 2011
2(a)(2)	Tri-band phosphor with normal lifetime and a tube diameter \geq 9 mm and \leq 17 mm (e.g. T5): 5 mg	Expires on 31 December 2011; 3 mg may be used per lamp after 31 December 2011
2(a)(3)	Tri-band phosphor with normal lifetime and a tube diameter > 17 mm and \leq 28 mm (e.g. T8): 5 mg	Expires on 31 December 2011; 3,5 mg may be used per lamp after 31 December 2011
2(a)(4)	Tri-band phosphor with normal lifetime and a tube diameter > 28 mm (e.g. T12): 5 mg	Expires on 31 December 2012; 3,5 mg may be used per lamp after 31 December 2012
2(a)(5)	Tri-band phosphor with long lifetime (\geq 25 000 h): 8 mg	Expires on 31 December 2011; 5 mg may be used per lamp after 31 December 2011
2(b)	Mercury in other fluorescent lamps not exceeding (per lamp):	
2(b)(1)	Linear halophosphate lamps with tube > 28 mm (e.g. T10 and T12): 10 mg	Expires on 13 April 2012
2(b)(2)	Non-linear halophosphate lamps (all diameters): 15 mg	Expires on 13 April 2016
2(b)(3)	Non-linear tri-band phosphor lamps with tube diameter > 17 mm (e.g. T9)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
2(b)(4)	Lamps for other general lighting and special purposes (e.g. induction lamps)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011

Exemption		Scope and dates of applicability
3	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp):	
3(a)	Short length (≤ 500 mm)	No limitation of use until 31 December 2011; 3,5 mg may be used per lamp after 31 December 2011
3(b)	Medium length (> 500 mm and $\leq 1\ 500$ mm)	No limitation of use until 31 December 2011; 5 mg may be used per lamp after 31 December 2011
3(c)	Long length ($> 1\ 500$ mm)	No limitation of use until 31 December 2011; 13 mg may be used per lamp after 31 December 2011
4(a)	Mercury in other low pressure discharge lamps (per lamp)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
4(b)	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index $R_a > 60$:	
4(b)-I	$P \leq 155$ W	No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011
4(b)-II	155 W $< P \leq 405$ W	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(b)-III	$P > 405$ W	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(c)	Mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner):	
4(c)-I	$P \leq 155$ W	No limitation of use until 31 December 2011; 25 mg may be used per burner after 31 December 2011
4(c)-II	155 W $< P \leq 405$ W	No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011
4(c)-III	$P > 405$ W	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(d)	Mercury in High Pressure Mercury (vapour) lamps (HPMV)	Expires on 13 April 2015
4(e)	Mercury in metal halide lamps (MH)	
4(f)	Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	
5(a)	Lead in glass of cathode ray tubes	
5(b)	Lead in glass of fluorescent tubes not exceeding 0,2 % by weight	

Exemption		Scope and dates of applicability
6(a)	Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight	
6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight	
6(c)	Copper alloy containing up to 4 % lead by weight	
7(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead)	
7(b)	Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications	
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound	
7(c)-II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher	
7(c)-III	Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC	Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013
8(a)	Cadmium and its compounds in one shot pellet type thermal cut-offs	Expires on 1 January 2012 and after that date may be used in spare parts for EEE placed on the market before 1 January 2012
8(b)	Cadmium and its compounds in electrical contacts	
9	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution	
9(b)	Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications	
11(a)	Lead used in C-press compliant pin connector systems	May be used in spare parts for EEE placed on the market before 24 September 2010
11(b)	Lead used in other than C-press compliant pin connector systems	Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013
12	Lead as a coating material for the thermal conduction module C-ring	May be used in spare parts for EEE placed on the market before 24 September 2010
13(a)	Lead in white glasses used for optical applications	
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	
14	Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80 % and less than 85 % by weight	Expired on 1 January 2011 and after that date may be used in spare parts for EEE placed on the market before 1 January 2011

	Exemption	Scope and dates of applicability
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	
16	Lead in linear incandescent lamps with silicate coated tubes	Expires on 1 September 2013
17	Lead halide as radiant agent in high intensity discharge (HID) lamps used for professional reprography applications	
18(a)	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as speciality lamps for diazoprinting reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ((Sr,Ba) ₂ MgSi ₂ O ₇ :Pb)	Expired on 1 January 2011
18(b)	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi ₂ O ₅ :Pb)	
19	Lead with PbBiSn-Hg and PbInSn-Hg in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact energy saving lamps (ESL)	Expires on 1 June 2011
20	Lead oxide in glass used for bonding front and rear substrates of flat fluorescent lamps used for Liquid Crystal Displays (LCDs)	Expires on 1 June 2011
21	Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses	
23	Lead in finishes of fine pitch components other than connectors with a pitch of 0,65 mm and less	May be used in spare parts for EEE placed on the market before 24 September 2010
24	Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors	
25	Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring	
26	Lead oxide in the glass envelope of black light blue lamps	Expires on 1 June 2011
27	Lead alloys as solder for transducers used in high-powered (designated to operate for several hours at acoustic power levels of 125 dB SPL and above) loudspeakers	Expired on 24 September 2010
29	Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC ⁽¹⁾	
30	Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more	
31	Lead in soldering materials in mercury free flat fluorescent lamps (which, e.g. are used for liquid crystal displays, design or industrial lighting)	
32	Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes	

Exemption		Scope and dates of applicability
33	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers	
34	Lead in cermet-based trimmer potentiometer elements	
36	Mercury used as a cathode sputtering inhibitor in DC plasma displays with a content up to 30 mg per display	Expired on 1 July 2010
37	Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body	
38	Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide	
39	Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm ² of light-emitting area) for use in solid state illumination or display systems	Expires on 1 July 2014

(¹) OJ L 326, 29.12.1969, p. 36.

ANNEX IV

Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments

Equipment utilising or detecting ionising radiation

1. Lead, cadmium and mercury in detectors for ionising radiation.
2. Lead bearings in X-ray tubes.
3. Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.
4. Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.
5. Lead in shielding for ionising radiation.
6. Lead in X-ray test objects.
7. Lead stearate X-ray diffraction crystals.
8. Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers.

Sensors, detectors and electrodes

- 1a. Lead and cadmium in ion selective electrodes including glass of pH electrodes.
- 1b. Lead anodes in electrochemical oxygen sensors.
- 1c. Lead, cadmium and mercury in infra-red light detectors.
- 1d. Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.

Others

9. Cadmium in helium-cadmium lasers.
 10. Lead and cadmium in atomic absorption spectroscopy lamps.
 11. Lead in alloys as a superconductor and thermal conductor in MRI.
 12. Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors.
 13. Lead in counterweights.
 14. Lead in single crystal piezoelectric materials for ultrasonic transducers.
 15. Lead in solders for bonding to ultrasonic transducers.
 16. Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay.
 17. Lead in solders in portable emergency defibrillators.
 18. Lead in solders of high performance infrared imaging modules to detect in the range 8-14 μm .
 19. Lead in Liquid crystal on silicon (LCoS) displays.
 20. Cadmium in X-ray measurement filters.
-

ANNEX V

Applications for granting, renewing and revoking exemptions as referred to in Article 5

Applications for exemptions, renewal of exemptions or, *mutatis mutandis*, for revoking an exemption may be submitted by a manufacturer, the authorised representative of a manufacturer, or any economic operator in the supply chain and shall include at least the following:

- (a) the name, address and contact details of the applicant;
 - (b) information on the material or component and the specific uses of the substance in the material and component for which an exemption, or its revocation, is requested and its particular characteristics;
 - (c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in Article 5;
 - (d) an analysis of possible alternative substances, materials or designs on a life-cycle basis, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;
 - (e) information on the possible preparation for reuse or recycling of materials from waste EEE, and on the provisions relating to the appropriate treatment of waste according to Annex II to Directive 2002/96/EC;
 - (f) other relevant information;
 - (g) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;
 - (h) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
 - (i) when applying for an exemption, proposal for a precise and clear wording for the exemption;
 - (j) a summary of the application.
-

ANNEX VI

EU DECLARATION OF CONFORMITY

1. No ... (unique identification of the EEE):
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 (or installer):
4. Object of the declaration (identification of EEE allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (*):
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
7. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

(*) OJ L 174, 1.7.2011, p. 88.

ANNEX VII

PART A

Repealed Directive with its successive amendments

(referred to in Article 26)

Directive 2002/95/EC of the European Parliament and of the Council	(OJ L 37, 13.2.2003, p. 19).
Commission Decision 2005/618/EC	(OJ L 214, 19.8.2005, p. 65).
Commission Decision 2005/717/EC	(OJ L 271, 15.10.2005, p. 48).
Commission Decision 2005/747/EC	(OJ L 280, 25.10.2005, p. 18).
Commission Decision 2006/310/EC	(OJ L 115, 28.4.2006, p. 38).
Commission Decision 2006/690/EC	(OJ L 283, 14.10.2006, p. 47).
Commission Decision 2006/691/EC	(OJ L 283, 14.10.2006, p. 48).
Commission Decision 2006/692/EC	(OJ L 283, 14.10.2006, p. 50).
Directive 2008/35/EC of the European Parliament and of the Council	(OJ L 81, 20.3.2008, p. 67).
Commission Decision 2008/385/EC	(OJ L 136, 24.5.2008, p. 9).
Commission Decision 2009/428/EC	(OJ L 139, 5.6.2009, p. 32).
Commission Decision 2009/443/EC	(OJ L 148, 11.6.2009, p. 27).
Commission Decision 2010/122/EU	(OJ L 49, 26.2.2010, p. 32).
Commission Decision 2010/571/EU	(OJ L 251, 25.9.2010, p. 28).

PART B

List of time-limits for transposition into national law

(referred to in Article 26)

Directive	Deadline for transposition
2002/95/EC	12 August 2004
2008/35/EC	—

ANNEX VIII

Correlation table

Directive 2002/95/EC	This Directive
Article 1	Article 1
Article 2(1)	Article 2(1), 2(2), Annex I
Article 2(2)	Article 2(3)
Article 2(3)	Article 2(4), introductory wording
—	Article 2(4)
Article 3(a)	Article 3(1),(2)
Article 3(b)	—
—	Article 3(6)-(28)
Article 4(1)	Article 4(1), Annex II
—	Article 4(3)-(4)
Article 4(2)	Article 4(6)
Article 4(3)	—
Article 5(1), introductory wording	Article 5(1), introductory wording
Article 5(1)(a)	Article 4(2)
Article 5(1)(b)	Article 5(1)(a), first and third indents
—	Article 5(1)(a), second indent Article 5(1)(a), final paragraph
Article 5(1)(c)	Article 5(1)(b)
—	Article 5(2) Article 5(3)-(6)
Article 5(2)	Article 5(7)
—	Article 5(8)
Article 6	Article 6
—	Article 7-18
Article 7	Articles 19-22
Article 8	Article 23
Article 9	Article 25
—	Article 26
Article 10	Article 27
Article 11	Article 28
—	Annexes I-II
Annex, points 1-39	Annex III, points 1-39
—	Annexes IV, V, VI-VIII

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