

Official Journal of the European Union

L 158



English edition

Legislation

Volume 57

27 May 2014

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I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) In a clinical trial the rights, safety, dignity and well-being of subjects should be protected and the data generated should be reliable and robust. The interests of the subjects should always take priority over all other interests.
- (2) In order to allow for independent control as to whether these principles are adhered to, a clinical trial should be subject to prior authorisation.
- (3) The existing definition of a clinical trial as contained in Directive 2001/20/EC of the European Parliament and of the Council ⁽³⁾ should be clarified. For that purpose, the concept of clinical trial should be more precisely defined by introducing the broader concept of 'clinical study' of which the clinical trial is a category. That category should be defined on the basis of specific criteria. This approach takes due account of international guidelines, and is in line with the Union law governing medicinal products, which builds on the dichotomy of 'clinical trial' and 'non-interventional study'.
- (4) Directive 2001/20/EC aims to simplify and harmonise the administrative provisions governing clinical trials in the Union. However, experience shows that a harmonised approach to the regulation of clinical trials has only been partly achieved. This makes it in particular difficult to perform a given clinical trial in several Member

⁽¹⁾ OJ C 44, 15.2.2013, p. 99.

⁽²⁾ Position of the European Parliament of 3 April 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

⁽³⁾ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

States. Scientific development, however, suggests that future clinical trials will target more specific patient populations, such as subgroups identified through genomic information. In order to include a sufficient number of patients for such clinical trials it may be necessary to involve many, or all, Member States. The new procedures for the authorisation of clinical trials should stimulate the inclusion of as many Member States as possible. Therefore, in order to simplify the procedures for the submission of an application dossier for the authorisation of a clinical trial, the multiple submission of largely identical information should be avoided and replaced by the submission of one application dossier to all the Member States concerned through a single submission portal. Given that clinical trials carried out in a single Member State are equally important to European clinical research, the application dossier for such clinical trials should also be submitted through that single portal.

- (5) As regards Directive 2001/20/EC, experience also indicates that the legal form of a Regulation would present advantages for sponsors and investigators, for example in the context of clinical trials taking place in more than one Member State, since they will be able to rely on its provisions directly, but also in the context of safety reporting and labelling of investigational medicinal products. Divergences of approach among different Member States will be therefore kept to a minimum.
- (6) The Member States concerned should cooperate in assessing a request for authorisation of a clinical trial. This cooperation should not include aspects of an intrinsically national nature, such as informed consent.
- (7) In order to avoid administrative delays for starting a clinical trial, the procedure to be used should be flexible and efficient, without compromising patient safety or public health.
- (8) The timelines for assessing an application dossier for clinical trials should be sufficient to assess the file while, at the same time, ensuring quick access to new, innovative treatments and ensuring that the Union remains an attractive place for conducting clinical trials. Against this background, Directive 2001/20/EC introduced the concept of tacit authorisation. This concept should be maintained in order to ensure that timelines are adhered to. In the event of a public health crisis, Member States should have the possibility to assess and authorise a clinical trial application swiftly. No minimal timelines for approval should therefore be established.
- (9) Clinical trials for the development of orphan medicinal products as defined in Regulation (EC) No 141/2000 of the European Parliament and of the Council ⁽¹⁾ and of medicinal products addressed to subjects affected by severe, debilitating and often life-threatening diseases affecting no more than one person in 50 000 in the Union (ultra-rare diseases) should be fostered.
- (10) Member States should efficiently assess all clinical trials applications within the given timelines. A rapid yet in-depth assessment is of particular importance for clinical trials concerning medical conditions which are severely debilitating and/or life threatening and for which therapeutic options are limited or non-existent, as in the case of rare and ultra-rare diseases.
- (11) The risk to subject safety in a clinical trial mainly stems from two sources: the investigational medicinal product and the intervention. Many clinical trials, however, pose only a minimal additional risk to subject safety compared to normal clinical practice. This is particularly the case where the investigational medicinal product is covered by a marketing authorisation, that is the quality, safety and efficacy has already been assessed in the course of the marketing authorisation procedure” or, if that product is not used in accordance with the terms of the marketing authorisation, that use is evidence-based and supported by published scientific evidence on the safety and efficacy of that product, and the intervention poses only very limited additional risk to the subject compared to normal clinical practice. Those low-intervention clinical trials are often of crucial importance for assessing standard treatments and diagnoses, thereby optimising the use of medicinal products and thus contributing to a high level of public health. Those clinical trials should be subject to less stringent rules, as regards monitoring, requirements for the contents of the master file and traceability of investigational medicinal products. In order to ensure subject safety they should however be subject to the same application procedure as any other clinical trial. The published scientific evidence supporting the safety and efficacy of an investigational medicinal product not used in accordance with the terms of the marketing authorisation could include high quality data published in scientific journal articles, as well as national, regional or institutional treatment protocols, health technology assessment reports or other appropriate evidence.

⁽¹⁾ Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

- (12) The Recommendation of the Organisation for Economic Cooperation and Development (OECD) Council on the Governance of Clinical Trials of 10 December 2012 introduced different risk categories for clinical trials. Those categories are compatible with the categories of clinical trials defined in this Regulation as the OECD Categories A and B(1) correspond to the definition of a low-intervention clinical trial as set out in this Regulation, and the OECD Categories B(2) and C correspond to the definition of a clinical trial as set out in this Regulation.
- (13) The assessment of the application for a clinical trial should address in particular the anticipated therapeutic and public health benefits (relevance) and the risk and inconvenience for the subject. In respect of the relevance, various aspects should be taken into account, including whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment of medicinal products and the authorisation of their placing on the market and whether surrogate end-points, when they are used, are justified.
- (14) Unless otherwise justified in the protocol, the subjects participating in a clinical trial should represent the population groups, for example gender and age groups, that are likely to use the medicinal product investigated in the clinical trial.
- (15) In order to improve treatments available for vulnerable groups such as frail or older people, people suffering from multiple chronic conditions, and people affected by mental health disorders, medicinal products which are likely to be of significant clinical value should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups.
- (16) The authorisation procedure should provide for the possibility to extend the timelines for the assessment in order to allow the sponsor to address questions or comments raised during the assessment of the application dossier. Moreover, it should be ensured that, within the extension period, there is always sufficient time for assessing the additional information submitted.
- (17) The authorisation to conduct a clinical trial should address all aspects of subject protection and data reliability and robustness. That authorisation should therefore be contained in a single administrative decision by the Member State concerned.
- (18) It should be left to the Member State concerned to determine the appropriate body or bodies to be involved in the assessment of the application to conduct a clinical trial and to organise the involvement of ethics committees within the timelines for the authorisation of that clinical trial as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. When determining the appropriate body or bodies, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available. In accordance with international guidelines, the assessment should be done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. The persons assessing the application should be independent of the sponsor, the clinical trial site, and the investigators involved, as well as free from any other undue influence.
- (19) The assessment of applications for the authorisation of clinical trials should be conducted on the basis of appropriate expertise. Specific expertise should be considered when assessing clinical trials involving subjects in emergency situations, minors, incapacitated subjects, pregnant and breastfeeding women and, where appropriate, other identified specific population groups, such as elderly people or people suffering from rare and ultra rare diseases.
- (20) In practice, sponsors do not always have all the information needed for submitting a complete application for authorisation of a clinical trial in all of the Member States where a clinical trial is eventually going to be conducted. It should be possible for sponsors to submit an application solely on the basis of documents assessed jointly by those Member States where the clinical trial might be conducted.
- (21) The sponsor should be allowed to withdraw the application for authorisation of a clinical trial. To ensure the reliable functioning of the assessment procedure, however, an application for authorisation of a clinical trial should be withdrawn only for the entire clinical trial. It should be possible for the sponsor to submit a new application for authorisation of a clinical trial following the withdrawal of an application.

- (22) In practice, in order to reach recruitment targets or for other reasons, sponsors may have an interest in extending the clinical trial to an additional Member States after the initial authorisation of the clinical trial. An authorisation mechanism should be provided to allow for such extension, while avoiding the re-assessment of the application by all the Member States concerned which were involved in the initial authorisation of the clinical trial.
- (23) Clinical trials are usually subject to many modifications after they have been authorised. Those modifications may relate to the conduct, the design, the methodology, the investigational or auxiliary medicinal product, or the investigator or clinical trial site involved. Where those modifications have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial, they should be subject to an authorisation procedure similar to the initial authorisation procedure.
- (24) The content of the application dossier for authorisation of a clinical trial should be harmonised in order to ensure that all Member States have the same information available and to simplify the application process for clinical trials.
- (25) In order to increase transparency in the area of clinical trials, data from a clinical trial should only be submitted in support of a clinical trial application if that clinical trial has been recorded in a publicly accessible and free of charge database which is a primary or partner registry of, or a data provider to, the international clinical trials registry platform of the World Health Organization (WHO ICTRP). Data providers to the WHO ICTRP create and manage clinical trial records in a manner that is consistent with the WHO registry criteria. Specific provision should be made for data from clinical trials started before the date of application of this Regulation.
- (26) It should be left to Member States to establish the language requirements for the application dossier. To ensure that the assessment of the application for authorisation of a clinical trial functions smoothly, Member States should consider accepting a commonly understood language in the medical field as the language for the documentation not destined for the subject.
- (27) Human dignity and the right to the integrity of the person are recognised in the Charter of Fundamental Rights of the European Union (the 'Charter'). In particular, the Charter requires that any intervention in the field of biology and medicine cannot be performed without free and informed consent of the person concerned. Directive 2001/20/EC contains an extensive set of rules for the protection of subjects. These rules should be upheld. Regarding the rules concerning the determination of the legally designated representatives of incapacitated persons and minors, those rules diverge in Member States. It should therefore be left to Member States to determine the legally designated representatives of incapacitated persons and minors. Incapacitated subjects, minors, pregnant women and breastfeeding women require specific protection measures.
- (28) An appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner should be responsible for all medical care provided to the subject, including the medical care provided by other medical staff.
- (29) It is appropriate that universities and other research institutions, under certain circumstances that are in accordance with the applicable law on data protection, be able to collect data from clinical trials to be used for future scientific research, for example for medical, natural or social sciences research purposes. In order to collect data for such purposes it is necessary that the subject gives consent to use his or her data outside the protocol of the clinical trial and has the right to withdraw that consent at any time. It is also necessary that research projects based on such data be made subject to reviews that are appropriate for research on human data, for example on ethical aspects, before being conducted.
- (30) In accordance with international guidelines, the informed consent of a subject should be in writing. When the subject is unable to write, it may be recorded through appropriate alternative means, for instance through audio or video recorders. Prior to obtaining informed consent, the potential subject should receive information in a prior interview in a language which is easily understood by him or her. The subject should have the opportunity to ask questions at any moment. Adequate time should be provided for the subject to consider his or her decision. In view of the fact that in certain Member States the only person qualified under national law to perform an interview with a potential subject is a medical doctor while in other Member States this is done by other professionals, it is appropriate to provide that the prior interview with a potential subject should be performed by a member of the investigating team qualified for this task under the national law of the Member State where the recruitment takes place.

- (31) In order to certify that informed consent is given freely, the investigator should take into account all relevant circumstances which might influence the decision of a potential subject to participate in a clinical trial, in particular whether the potential subject belongs to an economically or socially disadvantaged group or is in a situation of institutional or hierarchical dependency that could inappropriately influence her or his decision to participate.
- (32) This Regulation should be without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, should himself or herself assent in order to participate in a clinical trial.
- (33) It is appropriate to allow that informed consent be obtained by simplified means for certain clinical trials where the methodology of the trial requires that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products. In those clinical trials the investigational medicinal products are used in accordance with the marketing authorisations, and the individual subject receives a standard treatment regardless of whether he or she accepts or refuses to participate in the clinical trial, or withdraws from it, so that the only consequence of non-participation is that data relating to him or her are not used for the clinical trial. Such clinical trials, which serve to compare established treatments, should always be conducted within a single Member State.
- (34) Specific provisions should be defined for the protection of pregnant and breastfeeding women participating in clinical trials and in particular when the clinical trial does not have the potential to produce results of direct benefit to her or to her embryo, foetus or child after birth.
- (35) Persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in clinical trials, and persons, who due to their age, disability or state of health are reliant on care and for that reason accommodated in residential care institutions, that is accommodations providing an uninterrupted assistance for persons who necessitate such assistance, are in a situation of subordination or factual dependency and therefore may require specific protective measures. Member States should be allowed to maintain such additional measures.
- (36) This Regulation should provide for clear rules concerning informed consent in emergency situations. Such situations relate to cases where for example a patient has suffered a sudden life-threatening medical condition due to multiple traumas, strokes or heart attacks, necessitating immediate medical intervention. For such cases, intervention within an ongoing clinical trial, which has already been approved, may be pertinent. However, in certain emergency situations, it is not possible to obtain informed consent prior to the intervention. This Regulation should therefore set clear rules whereby such patients may be enrolled in the clinical trial under very strict conditions. In addition, the said clinical trial should relate directly to the medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative. Any previously expressed objection by the patient should be respected, and informed consent from the subject or from his or her legally designated representative should be sought as soon as possible.
- (37) In order to allow patients to assess possibilities to participate in a clinical trial, and to allow for effective supervision of a clinical trial by the Member State concerned, the start of the clinical trial, the end of the recruitment of subjects for the clinical trial and the end of the clinical trial should be notified. In accordance with international standards, the results of the clinical trial should be reported within one year from the end of the clinical trial.
- (38) The date of the first act of recruitment of a potential subject is the date on which the first act of the recruitment strategy described in the protocol was performed, e. g. the date of a contact with a potential subject or the date of the publication of an advertisement for a particular clinical trial.
- (39) The sponsor should submit a summary of the results of the clinical trial together with a summary that is understandable to a layperson, and the clinical study report, where applicable, within the defined timelines. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, for example when the clinical trial is still ongoing in third countries and data from that part of the trial are not available, which makes a statistical analysis not relevant, the sponsor should justify this in the protocol and specify when the results are going to be submitted.

- (40) In order for the sponsor to assess all potentially relevant safety information, the investigator should, as a rule, report to him all serious adverse events.
- (41) The sponsor should assess the information received from the investigator, and report safety information on serious adverse events which are suspected unexpected serious adverse reactions to the European Medicines Agency ('the Agency').
- (42) The Agency should forward that information to the Member States for them to assess it.
- (43) The members of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have agreed on a detailed set of guidelines on good clinical practice which is an internationally accepted standard for designing, conducting, recording and reporting clinical trials, consistent with principles that have their origin in the World Medical Association's Declaration of Helsinki. When designing, conducting, recording and reporting clinical trials, detailed questions may arise as to the appropriate quality standard. In such a case, the ICH guidelines on good clinical practice should be taken appropriately into account for the application of the rules set out in this Regulation, provided that there is no other specific guidance issued by the Commission and that those guidelines are compatible with this Regulation.
- (44) The conduct of a clinical trial should be adequately monitored by the sponsor in order to ensure the reliability and robustness of the results. Monitoring may also contribute to subject safety, taking into account the characteristics of the clinical trial and respect for fundamental rights of subjects. When establishing the extent of monitoring, the characteristics of the clinical trial should be taken into account.
- (45) The individuals involved in conducting a clinical trial, in particular investigators and other healthcare professionals, should be sufficiently qualified to perform their tasks, and the facilities where a clinical trial is to be conducted should be suitable for that clinical trial.
- (46) In order to ensure subject safety and the reliability and robustness of data from clinical trials, it is appropriate to provide that there should be arrangements for traceability, storage, return and destruction of investigational medicinal products, depending on the nature of the clinical trial. For the same reasons, there should also be such arrangements for unauthorised auxiliary medicinal products.
- (47) During a clinical trial, a sponsor may become aware of serious breaches of the rules for the conduct of that clinical trial. This should be reported to the Member States concerned in order for action to be taken by those Member States, where necessary.
- (48) Apart from the reporting of suspected unexpected serious adverse reactions, there may be other events which are relevant in terms of benefit-risk balance and which should be reported in a timely manner to the Member States concerned. It is important for subject safety that, in addition to serious adverse events and reactions, all unexpected events that might materially influence the benefit-risk assessment of the medicinal product or that would lead to changes in the administration of a medicinal product or in overall conduct of a clinical trial are notified to the Member States concerned. Examples of such unexpected events include an increase in the rate of occurrence of expected serious adverse reactions which may be clinically important, a significant hazard to the patient population, such as lack of efficacy of a medicinal product, or a major safety finding from a newly completed animal study (such as carcinogenicity).
- (49) Where unexpected events require an urgent modification of a clinical trial, it should be possible for the sponsor and the investigator to take urgent safety measures without awaiting prior authorisation. If such measures constitute a temporary halt of the clinical trial, the sponsor should apply for a substantial modification before restarting the clinical trial.
- (50) In order to ensure compliance of the conduct of a clinical trial with the protocol, and in order for investigators to be informed about the investigational medicinal products they administer, the sponsor should supply the investigators with an investigator's brochure.

- (51) The information generated in a clinical trial should be recorded, handled and stored adequately for the purpose of ensuring subject rights and safety, the robustness and reliability of the data generated in the clinical trial, accurate reporting and interpretation, effective monitoring by the sponsor and effective inspection by Member States.
- (52) In order to be able to demonstrate compliance with the protocol and with this Regulation, a clinical trial master file, containing relevant documentation to allow effective supervision (monitoring by the sponsor and inspection by Member States), should be kept by the sponsor and by the investigator. The clinical trial master file should be archived appropriately to allow for supervision after the clinical trial has ended.
- (53) Where there are problems with respect to the availability of authorised auxiliary medicinal products, unauthorised auxiliary medicinal products may be used in a clinical trial in justified cases. The price of the authorised auxiliary medicinal product should not be considered as having an effect on the availability of such medicinal products.
- (54) Medicinal products intended for research and development trials fall outside the scope of Directive 2001/83/EC of the European Parliament and of the Council ⁽¹⁾. Such medicinal products include medicinal products used in the context of a clinical trial. They should be covered by specific rules taking account of their peculiarities. In establishing these rules, a distinction should be made between investigational medicinal products (the tested product and its reference products, including placebos) and auxiliary medicinal products (medicinal products used in the context of a clinical trial but not as investigational medicinal products), such as medicinal products used for background treatment, challenge agents, rescue medication, or used to assess end-points in a clinical trial. Auxiliary medicinal products should not include concomitant medications, that is medications unrelated to the clinical trial and not relevant for the design of the clinical trial.
- (55) In order to ensure subject safety and the reliability and robustness of data generated in a clinical trial, and in order to allow for the distribution of investigational and auxiliary medicinal products to clinical trial sites throughout the Union, rules on the manufacturing and import of both investigational and auxiliary medicinal products should be established. As is already the case for Directive 2001/20/EC, those rules should reflect the existing rules of good manufacturing practices for products covered by Directive 2001/83/EC. In some specific cases, it should be possible to allow deviations from those rules in order to facilitate the conduct of a clinical trial. Therefore, the applicable rules should allow for some flexibility, provided that subject safety, as well as reliability and robustness of the data generated in the clinical trial are not compromised.
- (56) The requirement to hold an authorisation for manufacture or import of investigational medicinal products should not apply to the preparation of investigational radiopharmaceuticals from radionuclide generators, kits or radionuclide precursors in accordance with the manufacturer's instructions for use in hospitals, health centres or clinics taking part in the same clinical trial in the same Member State.
- (57) Investigational and auxiliary medicinal products should be appropriately labelled in order to ensure subject safety and the reliability and robustness of data generated in clinical trials, and in order to allow for the distribution of those products to clinical trial sites throughout the Union. The rules for labelling should be adapted to the risks to subject safety and the reliability and robustness of data generated in clinical trials. Where the investigational or auxiliary medicinal product have already been placed on the market as an authorised medicinal product in accordance with Directive 2001/83/EC and Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽²⁾, as a general rule no additional labelling should be required for clinical trials that do not involve the blinding of the label. Moreover, there are specific products, such as radiopharmaceuticals used as diagnostic investigational medicinal product, where the general rules on labelling are inappropriate in view of the very controlled setting of the use of radiopharmaceuticals in clinical trials.
- (58) In order to ensure clear responsibilities, the concept of a 'sponsor' of a clinical trial, in line with international guidelines, was introduced by Directive 2001/20/EC. This concept should be upheld.
- (59) In practice, there may be loose, informal networks of researchers or research institutions which jointly conduct a clinical trial. Those networks should be able to be co-sponsors of a clinical trial. In order not to weaken the

⁽¹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁽²⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1.)

concept of responsibility in a clinical trial, where a clinical trial has several sponsors, they should all be subject to the obligations of a sponsor under this Regulation. However, the co-sponsors should be able to split up the responsibilities of the sponsor by contractual agreement.

- (60) In order to ensure that enforcement action may be taken by Member States and that legal proceedings may be brought in appropriate cases, it is appropriate to provide that sponsors that are not established in the Union should be represented by a legal representative in the Union. However in view of the divergent approaches of the Member States as regards civil and criminal liability, it is appropriate to leave to each Member State concerned, as regards its territory, the choice as to whether or not to require such a legal representative, provided that at least a contact person is established in the Union.
- (61) Where, in the course of a clinical trial, damage caused to the subject leads to the civil or criminal liability of the investigator or the sponsor, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.
- (62) In clinical trials compensation should be ensured for damages successfully claimed in accordance with the applicable laws. Therefore Member States should ensure that systems for compensation for damages suffered by a subject are in place which are appropriate to the nature and the extent of the risk.
- (63) The Member State concerned should be given the power to revoke the authorisation of a clinical trial, suspend a clinical trial or require the sponsor to modify a clinical trial.
- (64) In order to ensure compliance with this Regulation, Member States should be able to conduct inspections and should have adequate inspection capacities.
- (65) The Commission should be able to control whether Member States correctly supervise compliance with this Regulation. Moreover, the Commission should be able to control whether regulatory systems of third countries ensure compliance with the specific provisions of this Regulation and Directive 2001/83/EC concerning clinical trials conducted in third countries.
- (66) In order to streamline and facilitate the flow of information between sponsors and Member States as well as between Member States, the Agency should, in collaboration with Member States and the Commission, set up and maintain an EU database, accessed through an EU portal.
- (67) In order to ensure a sufficient level of transparency in the clinical trials, the EU database should contain all relevant information as regards the clinical trial submitted through the EU portal. The EU database should be publicly accessible and data should be presented in an easily searchable format, with related data and documents linked together by the EU trial number and with hyperlinks, for example linking together the summary, the layperson's summary, the protocol and the clinical study report of one clinical trial, as well as linking to data from other clinical trials which used the same investigational medicinal product. All clinical trials should be registered in the EU database prior to being started. As a rule, the start and end dates of the recruitment of subjects should also be published in the EU database. No personal data of data subjects participating in a clinical trial should be recorded in the EU database. The information in the EU database should be public, unless specific reasons require that a piece of information should not be published, in order to protect the right of the individual to private life and the right to the protection of personal data, recognised by Articles 7 and 8 of the Charter. Publicly available information contained in the EU database should contribute to protecting public health and fostering the innovation capacity of European medical research, while recognising the legitimate economic interests of sponsors.
- (68) For the purposes of this Regulation, in general the data included in a clinical study report should not be considered commercially confidential once a marketing authorisation has been granted, the procedure for granting

the marketing authorisation has been completed, the application for marketing authorisation has been withdrawn. In addition, the main characteristics of a clinical trial, the conclusion on Part I of the assessment report for the authorisation of a clinical trial, the decision on the authorisation of a clinical trial, the substantial modification of a clinical trial, and the clinical trial results including reasons for temporary halt and early termination, in general, should not be considered confidential.

- (69) Within a Member State, there may be several bodies involved in the authorisation of clinical trials. In order to allow for effective and efficient cooperation between Member States, each Member State should designate one contact point.
- (70) The authorisation procedure set out in this Regulation is largely controlled by Member States. Nevertheless, the Commission and the Agency should support the good functioning of that procedure, in accordance with this Regulation.
- (71) In order to carry out the activities provided for in this Regulation, Member States should be allowed to levy fees. However, Member States should not require multiple payments to different bodies involved in the assessment, in a given Member State, of an application for authorisation of a clinical trial.
- (72) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in respect of the establishment and modification of rules on cooperation between the Member States when assessing the information provided by the sponsor on the Eudravigilance database and the specification of detailed arrangements for inspection procedures. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (73) In order to supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of: the amendment of Annexes I, II, IV and V to this Regulation in order to adapt them to technical progress or to take account of international regulatory developments in which the Union or the Member States are involved, in the field of clinical trials; the amendment of Annex III in order to improve the information on the safety of medicinal products, to adapt technical requirements to technical progress or to take account of international regulatory developments in the field of safety requirements in clinical trials endorsed by bodies in which the Union or the Member States participate; the specification of the principles and guidelines of good manufacturing practice and the detailed arrangements for inspection for ensuring the quality of investigational medicinal products; the amendment of Annex VI in order to ensure subject safety and the reliability and robustness of data generated in a clinical trial or to take account of technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (74) Directive 2001/83/EC provides that that Directive does not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products as abortifacients. Directive 2001/83/EC provides that national legislation prohibiting or restricting the use of any specific type of human or animal cells is not, in principle, affected by either that Directive or any of the Regulations referred to therein. Likewise, this Regulation should not affect national law prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products used as abortifacients. In addition, this Regulation should not affect national law prohibiting or restricting the sale, supply or use of medicinal products containing narcotic substances within the meaning of the relevant international conventions in force such as the Single Convention on Narcotic Drugs of 1954 of the United Nations. Member States should communicate those national provisions to the Commission.
- (75) Directive 2001/20/EC provides that no gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity. It is appropriate to maintain that provision.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (76) Directive 95/46/EC of the European Parliament and of the Council ⁽¹⁾ applies to the processing of personal data carried out in the Member States within the framework of this Regulation, under the supervision of the Member States competent authorities, in particular the public independent authorities designated by the Member States and Regulation (EC) No 45/2001 of the European Parliament and of the Council ⁽²⁾ applies to the processing of personal data carried out by the Commission and the Agency within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. Those instruments strengthen personal data protection rights, encompassing the right to access, rectification and withdrawal, as well as specify the situations when restriction on those rights may be imposed. With a view to respecting those rights, while safeguarding the robustness and reliability of data from clinical trials used for scientific purposes and the safety of subjects participating in clinical trials, it is appropriate to provide that, without prejudice to Directive 95/46/EC, the withdrawal of informed consent should not affect the results of activities already carried out, such as the storage and use of data obtained on the basis of informed consent before withdrawal.
- (77) Subjects should not have to pay for investigational medicinal products, auxiliary medicinal products, medical devices used for their administration and procedures specifically required by the protocol, unless the law of the Member State concerned provides otherwise.
- (78) The authorisation procedure set out in this Regulation should apply as soon as possible, in order for sponsors to reap the benefits of a streamlined authorisation procedure. However, in view of the importance of the extensive IT functionalities required for the authorisation procedure, it is appropriate to provide that this Regulation should only become applicable once it has been verified that the EU portal and the EU database are fully functional.
- (79) Directive 2001/20/EC should be repealed to ensure that only one set of rules applies to the conduct of clinical trials in the Union. In order to facilitate the transition to the rules set out in this Regulation, sponsors should be allowed to start and conduct a clinical trial in accordance with Directive 2001/20/EC during a transitional period.
- (80) This Regulation is in line with the major international guidance documents on clinical trials, such as the 2008 version of the World Medical Association's Declaration of Helsinki and good clinical practice, which has its origins in the Declaration of Helsinki.
- (81) As regards Directive 2001/20/EC, experience also shows that a large proportion of clinical trials are conducted by non-commercial sponsors. Non-commercial sponsors frequently rely on funding which comes partly or entirely from public funds or charities. In order to maximise the valuable contribution of such non-commercial sponsors and to further stimulate their research but without compromising the quality of clinical trials, measures should be taken by Member States to encourage clinical trials conducted by those sponsors.
- (82) This Regulation is based on the double legal basis of Articles 114 and 168(4)(c) TFEU. It aims at achieving an internal market as regards clinical trials and medicinal products for human use, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medicinal products in order to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously. These two objectives are inseparably linked and one is not secondary to another. Regarding Article 114 TFEU, this Regulation harmonises the rules for the conduct of clinical trials in the Union, therefore ensuring the functioning of the internal market in view of the conduct of a clinical trial in several Member States, the acceptability throughout the Union of data generated in a clinical trial and submitted in the application for the authorisation of another clinical trial or of the placing on the market of a medicinal product, and the free movement of medicinal products used in the context of a clinical trial. Regarding Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medicinal products by ensuring that data generated in clinical trials are reliable and robust, thus ensuring that treatments and medicines which are intended to be an improvement of a treatment of patients build on reliable and robust data. Moreover, this Regulation sets high standards of quality and safety of medicinal products used in the context of a clinical trial, thus ensuring the safety of subjects in a clinical trial.

⁽¹⁾ 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 (OJ L 281, 23.11.1995, p. 31).

⁽²⁾ 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 (OJ L 8, 12.1.2001, p. 1).

- (83) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science. This Regulation should be applied by the Member States in accordance with those rights and principles.
- (84) The European Data Protection Supervisor has given an opinion ⁽¹⁾ pursuant to Article 28(2) of Regulation (EC) No 45/2001.
- (85) Since the objective of this Regulation, namely to ensure that, throughout the Union, clinical trial data are reliable and robust while ensuring respect for the rights, safety, dignity and well-being of subjects, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

This Regulation applies to all clinical trials conducted in the Union.

It does not apply to non-interventional studies.

Article 2

Definitions

1. For the purposes of this Regulation, the definitions of 'medicinal product', 'radiopharmaceutical', 'adverse reaction', 'serious adverse reaction', 'immediate packaging' and 'outer packaging' set out in points (2), (6), (11), (12), (23) and (24), respectively, of Article 1 of Directive 2001/83/EC apply.
2. For the purposes of this Regulation, the following definitions also apply:
 - (1) 'Clinical study' means any investigation in relation to humans intended:
 - (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
 - (b) to identify any adverse reactions to one or more medicinal products; or
 - (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;with the objective of ascertaining the safety and/or efficacy of those medicinal products;
 - (2) 'Clinical trial' means a clinical study which fulfils any of the following conditions:
 - (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;
 - (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or
 - (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

⁽¹⁾ OJ C 253, 3.9.2013, p. 10.

- (3) 'Low-intervention clinical trial' means a clinical trial which fulfils all of the following conditions:
- (a) the investigational medicinal products, excluding placebos, are authorised;
 - (b) according to the protocol of the clinical trial,
 - (i) the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or
 - (ii) the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and
 - (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;
- (4) 'Non-interventional study' means a clinical study other than a clinical trial;
- (5) 'Investigational medicinal product' means a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial;
- (6) 'Normal clinical practice' means the treatment regime typically followed to treat, prevent, or diagnose a disease or a disorder;
- (7) 'Advanced therapy investigational medicinal product' means an investigational medicinal product which is an advanced therapy medicinal product as defined in point (a) of Article 2(1) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council ⁽¹⁾;
- (8) 'Auxiliary medicinal product' means a medicinal product used for the needs of a clinical trial as described in the protocol, but not as an investigational medicinal product;
- (9) 'Authorised investigational medicinal product' means a medicinal product authorised in accordance with Regulation (EC) No 726/2004 or in any Member State concerned in accordance with Directive 2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an investigational medicinal product;
- (10) 'Authorised auxiliary medicinal product' means a medicinal product authorised in accordance with Regulation (EC) No 726/2004, or in any Member State concerned in accordance with Directive 2001/83/EC, irrespective of changes to the labelling of the medicinal product, which is used as an auxiliary medicinal product;
- (11) 'Ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;
- (12) 'Member State concerned' means the Member State where an application for authorisation of a clinical trial or of a substantial modification has been submitted under Chapters II or III of this Regulation respectively;
- (13) 'Substantial modification' means any change to any aspect of the clinical trial which is made after notification of a decision referred to in Articles 8, 14, 19, 20 or 23 and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial;
- (14) 'Sponsor' means an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial;

⁽¹⁾ Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

- (15) 'Investigator' means an individual responsible for the conduct of a clinical trial at a clinical trial site;
- (16) 'Principal investigator' means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site;
- (17) 'Subject' means an individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control;
- (18) 'Minor' means a subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent;
- (19) 'Incapacitated subject' means a subject who is, for reasons other than the age of legal competence to give informed consent, incapable of giving informed consent according to the law of the Member State concerned;
- (20) 'Legally designated representative' means a natural or legal person, authority or body which, according to the law of the Member State concerned, is empowered to give informed consent on behalf of a subject who is an incapacitated subject or a minor;
- (21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial;
- (22) 'Protocol' means a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial. The term 'protocol' encompasses successive versions of the protocol and protocol modifications;
- (23) 'Investigator's brochure' means a compilation of the clinical and non-clinical data on the investigational medicinal product or products which are relevant to the study of the product or products in humans;
- (24) 'Manufacturing' means total and partial manufacture, as well as the various processes of dividing up, packaging and labelling (including blinding);
- (25) 'Start of a clinical trial' means the first act of recruitment of a potential subject for a specific clinical trial, unless defined differently in the protocol;
- (26) 'End of a clinical trial' means the last visit of the last subject, or at a later point in time as defined in the protocol;
- (27) 'Early termination of a clinical trial' means the premature end of a clinical trial due to any reason before the conditions specified in the protocol are complied with;
- (28) 'Temporary halt of a clinical trial' means an interruption not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it;
- (29) 'Suspension of a clinical trial' means interruption of the conduct of a clinical trial by a Member State;
- (30) 'Good clinical practice' means a set of detailed ethical and scientific quality requirements for designing, conducting, performing, monitoring, auditing, recording, analysing and reporting clinical trials ensuring that the rights, safety and well-being of subjects are protected, and that the data generated in the clinical trial are reliable and robust;
- (31) 'Inspection' means the act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the clinical trial site, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;

- (32) 'Adverse event' means any untoward medical occurrence in a subject to whom a medicinal product is administered and which does not necessarily have a causal relationship with this treatment;
- (33) 'Serious adverse event' means any untoward medical occurrence that at any dose requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death;
- (34) 'Unexpected serious adverse reaction' means a serious adverse reaction, the nature, severity or outcome of which is not consistent with the reference safety information;
- (35) 'Clinical study report' means a report on the clinical trial presented in an easily searchable format, prepared in accordance with Annex I, Part I, Module 5 of Directive 2001/83/EC and accompanying an application for marketing authorisation.
3. For the purposes of this Regulation, a subject who falls under the definition of both 'minor' and 'incapacitated subject' shall be deemed to be an incapacitated subject.

Article 3

General principle

A clinical trial may be conducted only if:

- (a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and
- (b) it is designed to generate reliable and robust data.

CHAPTER II

AUTHORISATION PROCEDURE FOR A CLINICAL TRIAL

Article 4

Prior authorisation

A clinical trial shall be subject to scientific and ethical review and shall be authorised in accordance with this Regulation.

The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The review by the ethics committee may encompass aspects addressed in Part I of the assessment report for the authorisation of a clinical trial as referred to in Article 6 and in Part II of that assessment report as referred to in Article 7 as appropriate for each Member State concerned.

Member States shall ensure that the timelines and procedures for the review by the ethics committees are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial.

Article 5

Submission of an application

1. In order to obtain an authorisation, the sponsor shall submit an application dossier to the intended Member States concerned through the portal referred to in Article 80 (the 'EU portal').

The sponsor shall propose one of the Member States concerned as reporting Member State.

If a Member State concerned other than the proposed reporting Member State is willing to be the reporting Member State or where the proposed reporting Member State does not wish to be the reporting Member State, this shall be notified through the EU portal to all Member States concerned not later than three days after the application dossier is submitted.

If only one Member State concerned is willing to be the reporting Member State or if the clinical trial involves only one Member State, that Member State shall be the reporting Member State.

If there is no Member State concerned willing to be the reporting Member State or if there is more than one Member State concerned willing to be the reporting Member State, the reporting Member State shall be selected by agreement among the Member States concerned taking into account the recommendations referred to in point (c) of Article 85(2).

If there is no agreement among the Member States concerned, the proposed reporting Member State shall be the reporting Member State.

The reporting Member State shall notify the sponsor and the other Member States concerned that it is the reporting Member State, through the EU portal, within six days from the submission of the application dossier.

2. The sponsor shall, when applying for a low-intervention clinical trial, where the investigational medicinal product is not used in accordance with the terms of the marketing authorisation but the use of that product is evidence-based and supported by published scientific evidence on the safety and efficacy of that product, propose one of the Member States concerned where the use is evidence-based, as reporting Member State.

3. Within 10 days from the submission of the application dossier, the reporting Member State shall validate the application taking into account considerations expressed by the other Member States concerned and notify the sponsor, through the EU portal, of the following:

(a) whether the clinical trial applied for falls within the scope of this Regulation;

(b) whether the application dossier is complete in accordance with Annex I;

Member States concerned may communicate to the reporting Member State any considerations relevant to the validation of the application within seven days from the submission of the application dossier.

4. Where the reporting Member State has not notified the sponsor within the period referred to in the first subparagraph of paragraph 3, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete.

5. Where the reporting Member State, taking into account considerations expressed by the other Member States concerned, finds that the application dossier is not complete, or that the clinical trial applied for does not fall within the scope of this Regulation, it shall inform the sponsor thereof through the EU portal and shall set a maximum of 10 days for the sponsor to comment on the application or to complete the application dossier through the EU portal.

Within five days from receipt of the comments or the completed application dossier, the reporting Member State shall notify the sponsor as to whether or not the application complies with the requirements set out in points (a) and (b) of the first subparagraph of paragraph 3.

Where the reporting Member State has not notified the sponsor within the period referred to in the second subparagraph, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete.

Where the sponsor has not provided comments or completed the application dossier within the period referred to in the first subparagraph, the application shall be deemed to have lapsed in all Member States concerned.

6. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 3 or 5 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the respective periods referred to in paragraphs 3 and 5.

Article 6

Assessment report — Aspects covered by Part I

1. The reporting Member State shall assess the application with regard to the following aspects:
 - (a) Whether the clinical trial is a low-intervention clinical trial, where claimed by the sponsor;
 - (b) Compliance with Chapter V with respect to the following:
 - (i) The anticipated therapeutic and public health benefits taking account of all of the following:
 - the characteristics of and knowledge about the investigational medicinal products;
 - the relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated, or if not, the explanation and justification provided in accordance with point (y) of paragraph 17 of Annex I to this Regulation; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; and, where applicable, any opinion formulated by the Paediatric Committee on a paediatric investigation plan in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council ⁽¹⁾;
 - the reliability and robustness of the data generated in the clinical trial, taking account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints;
 - (ii) The risks and inconveniences for the subject, taking account of all of the following:
 - the characteristics of and knowledge about the investigational medicinal products and the auxiliary medicinal products;
 - the characteristics of the intervention compared to normal clinical practice;
 - the safety measures, including provisions for risk minimisation measures, monitoring, safety reporting, and the safety plan;
 - the risk to subject health posed by the medical condition for which the investigational medicinal product is being investigated;
 - (c) Compliance with the requirements concerning the manufacturing and import of investigational medicinal products and auxiliary medicinal products set out in Chapter IX;
 - (d) Compliance with the labelling requirements set out in Chapter X;
 - (e) The completeness and adequateness of the investigator's brochure.
2. The reporting Member State shall draw up an assessment report. The assessment of the aspects referred to in paragraph 1 shall constitute Part I of the assessment report.
3. The assessment report shall contain one of the following conclusions concerning the aspects addressed in Part I of the assessment report:
 - (a) the conduct of the clinical trial is acceptable in view of the requirements set out in this Regulation;
 - (b) the conduct of the clinical trial is acceptable in view of the requirements set out in this Regulation, but subject to compliance with specific conditions which shall be specifically listed in that conclusion; or
 - (c) the conduct of the clinical trial is not acceptable in view of the requirements set out in this Regulation.
4. The reporting Member State shall submit, through the EU portal, the final Part I of the assessment report, including its conclusion, to the sponsor and to the other Member States concerned within 45 days from the validation date.

⁽¹⁾ Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.11.2006, p. 1).

5. For clinical trials involving more than one Member State, the assessment process shall include three phases:
 - (a) an initial assessment phase performed by the reporting Member State within 26 days from the validation date;
 - (b) a coordinated review phase performed within 12 days from the end of the initial assessment phase involving all Member States concerned;
 - (c) a consolidation phase performed by the reporting Member State within seven days from the end of coordinated review phase.

During the initial assessment phase, the reporting Member State shall develop a draft Part I of the assessment report and circulate it to all other Member States concerned.

During the coordinated review phase, all Member States concerned shall jointly review the application based on the draft Part I of the assessment report and shall share any considerations relevant to the application.

During the consolidation phase, the reporting Member State shall take due account of the considerations of the other Member States concerned when finalising Part I of the assessment report and shall record how all such considerations have been dealt with. The reporting Member State shall submit the final Part I of the assessment report to the sponsor and all other Member States concerned within the period referred to in paragraph 4.

6. For the purposes of this Chapter, the date on which the final Part I of the assessment report is submitted by the reporting Member State to the sponsor and to the other Member States concerned shall be the reporting date.

7. The reporting Member State may also extend the period referred to in paragraph 4 by a further 50 days for clinical trials involving an advanced therapy investigational medicinal products or a medicinal product as defined in point 1 of the Annex to Regulation (EC) No 726/2004, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 5 and 8 of this Article shall apply *mutatis mutandis*.

8. Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph 5.

For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the third and fourth subparagraph, the reporting Member State may extend the period referred to in paragraph 4 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the reporting Member State which shall not exceed 12 days from the receipt of the request.

Upon receipt of the additional information, the Member States concerned shall jointly review any additional information provided by the sponsor together with the original application and shall share any considerations relevant to the application. The coordinated review shall be performed within a maximum of 12 days of the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days of the end of coordinated review. When finalising Part I of the assessment report, the reporting Member State shall take due account of the considerations of the Member States concerned and shall record how all such considerations have been dealt with.

Where the sponsor does not provide additional information within the period set by the reporting Member State in accordance with the third subparagraph, the application shall be deemed to have lapsed in all Member States concerned.

The request for additional information and the additional information shall be submitted through the EU portal.

Article 7

Assessment report — Aspects covered by Part II

1. Each Member State concerned shall assess, for its own territory, the application with respect to the following aspects:
 - (a) compliance with the requirements for informed consent as set out in Chapter V;
 - (b) compliance of the arrangements for rewarding or compensating subjects with the requirements set out in Chapter V and investigators;

- (c) compliance of the arrangements for recruitment of subjects with the requirements set out in Chapter V;
- (d) compliance with Directive 95/46/EC;
- (e) compliance with Article 49;
- (f) compliance with Article 50;
- (g) compliance with Article 76;
- (h) compliance with the applicable rules for the collection, storage and future use of biological samples of the subject.

The assessment of the aspects referred to in the first subparagraph shall constitute Part II of the assessment report.

2. Each Member State concerned shall complete its assessment within 45 days from the validation date and submit, through the EU portal, Part II of the assessment report, including its conclusion, to the sponsor.

Each Member State concerned may request, with justified reasons, additional information from the sponsor regarding the aspects referred to in paragraph 1 only within the period referred to in the first subparagraph.

3. For the purpose of obtaining and reviewing the additional information referred to in the second subparagraph of paragraph 2 from the sponsor in accordance with the second and third subparagraph, the Member State concerned may extend the period referred to in the first subparagraph of paragraph 2 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the Member State concerned which shall not exceed 12 days from the receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of 19 days.

Where the sponsor does not provide additional information within the period set by the Member State concerned in accordance with the second subparagraph, the application shall be deemed to have lapsed in that Member State concerned.

The request for additional information and the additional information shall be submitted through the EU portal.

Article 8

Decision on the clinical trial

1. Each Member State concerned shall notify the sponsor through the EU portal as to whether the clinical trial is authorised, whether it is authorised subject to conditions, or whether authorisation is refused.

Notification shall be done by way of one single decision within five days from the reporting date or from the last day of the assessment referred to in Article 7, whichever is later.

An authorisation of a clinical trial subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

2. Where the conclusion of the reporting Member State as regards Part I of the assessment report is that the conduct of the clinical trial is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State concerned.

Notwithstanding the first subparagraph, a Member State concerned may disagree with the conclusion of the reporting Member State as regards Part I of the assessment report only on the following grounds:

- (a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
- (b) infringement of its national law as referred to in Article 90;
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 5 or 8 of Article 6.

Where a Member State concerned disagrees with the conclusion on the basis of the second subparagraph, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States, and to the sponsor.

3. Where, regarding the aspects covered by Part I of the assessment report, the clinical trial is acceptable or acceptable subject to compliance with specific conditions, the Member State concerned shall include in its decision its conclusion on Part II of the assessment report.

4. A Member State concerned shall refuse to authorise a clinical trial if it disagrees with the conclusion of the reporting Member State as regards Part I of the assessment report on any of the grounds referred to in the second subparagraph of paragraph 2, or if it finds, on duly justified grounds, that the aspects addressed in Part II of the assessment report are not complied with, or where an ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

5. Where the conclusion of the reporting Member State as regards Part I of the assessment report is that the clinical trial is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

6. Where the Member State concerned has not notified the sponsor of its decision within the relevant periods referred to in paragraph 1, the conclusion on Part I of the assessment report shall be deemed to be the decision of the Member State concerned on the application for authorisation of the clinical trial.

7. The Member States concerned shall not request additional information regarding the aspects addressed in Part I of the assessment report from the sponsor after the reporting date.

8. For the purposes of this Chapter, the notification date shall be the date on which the decision referred to in paragraph 1 is notified to the sponsor. Where the sponsor has not been notified in accordance with paragraph 1, the notification date shall be deemed to be the last day of the period provided for in paragraph 1.

9. If no subject has been included in the clinical trial in a Member State concerned within two years from the notification date of the authorisation, the authorisation shall expire in that Member State concerned unless an extension, on request of the sponsor, has been approved following the procedure set out in Chapter III.

Article 9

Persons assessing the application

1. Member States shall ensure that the persons validating and assessing the application do not have conflicts of interest, are independent of the sponsor, of the clinical trial site and the investigators involved and of persons financing the clinical trial, as well as free of any other undue influence.

In order to guarantee independence and transparency, the Member States shall ensure that persons admitting and assessing the application as regards the aspects addressed in Parts I and II of the assessment report have no financial or personal interests which could affect their impartiality. These persons shall make an annual declaration of their financial interests.

2. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.

3. At least one layperson shall participate in the assessment.

Article 10

Specific considerations for vulnerable populations

1. Where the subjects are minors, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial on the basis of paediatric expertise or after taking advice on clinical, ethical and psychosocial problems in the field of paediatrics.

2. Where the subjects are incapacitated subjects, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial on the basis of expertise in the relevant disease and the patient population concerned or after taking advice on clinical, ethical and psychosocial questions in the field of the relevant disease and the patient population concerned.
3. Where the subjects are pregnant or breastfeeding women, specific consideration shall be given to the assessment of the application for authorisation of a clinical trial on the basis of expertise in the relevant condition and the population represented by the subject concerned.
4. If according to the protocol a clinical trial provides for the participation of specific groups or subgroups of subjects, where appropriate, specific consideration shall be given to the assessment of the application for authorisation of that clinical trial on the basis of expertise in the population represented by the subjects concerned.
5. In any application for authorisation of a clinical trial referred to in Article 35, specific consideration shall be given to the circumstances of the conduct of the clinical trial.

Article 11

Submission and assessment of applications limited to aspects covered by Part I or Part II of the assessment report

Where the sponsor so requests, the application for authorisation of a clinical trial, its assessment and the conclusion shall be limited to the aspects covered by Part I of the assessment report.

After the notification of the conclusion on the aspects covered by Part I of the assessment report, the sponsor may within two years apply for an authorisation limited to aspects covered by Part II of the assessment report. In that application the sponsor shall declare that he is not aware of any new substantial scientific information that would change the validity of any item submitted in the application on the aspects covered by Part I of the assessment report. In this case, that application shall be assessed in accordance with Article 7 and the Member State concerned shall notify its decision on the clinical trial in accordance with Article 8. In those Member States where the sponsor does not apply for an authorisation limited to aspects covered by Part II of the assessment report within two years, the application on the aspects covered by Part I of the assessment report shall be deemed to have lapsed.

Article 12

Withdrawal

The sponsor may withdraw the application at any time until the reporting date. In such a case, the application may only be withdrawn with respect to all Member States concerned. The reasons for the withdrawal shall be communicated through the EU portal.

Article 13

Resubmission

This Chapter is without prejudice to the possibility for the sponsor to resubmit, following the refusal to grant an authorisation or the withdrawal of an application, an application for authorisation to any intended Member State concerned. That application shall be deemed to be a new application for authorisation of another clinical trial.

Article 14

Subsequent addition of a Member State concerned

1. Where the sponsor wishes to extend an authorised clinical trial to another Member State ('additional Member State concerned'), the sponsor shall submit an application dossier to that Member State through the EU portal.

The application dossier may be submitted only after the notification date of the initial authorisation decision.

2. The reporting Member State for the application dossier referred to in paragraph 1 shall be the reporting Member State for the initial authorisation procedure.

3. The additional Member State concerned shall notify the sponsor through the EU portal, within 52 days from the date of submission of the application dossier referred to in paragraph 1, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to conditions, or whether the authorisation is refused.

An authorisation of a clinical trial subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

4. Where the conclusion of the reporting Member State as regards Part I of the assessment report is that the conduct of the clinical trial is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the additional Member State concerned.

Notwithstanding the first subparagraph, an additional Member State concerned may disagree with the conclusion of the reporting Member State as regards Part I of the assessment report only on the following grounds:

- (a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
- (b) infringement of its national law as referred to in Article 90;
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 5 or 6.

Where an additional Member State concerned disagrees with the conclusion on the basis of the second subparagraph, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States, and to the sponsor.

5. Between the date of submission of the application dossier referred to in paragraph 1 and five days before the expiry of the period referred to in paragraph 3, the additional Member State concerned may communicate to the reporting Member State and the other Member States concerned any considerations relevant to the application through the EU portal.

6. Between the date of submission of the application dossier referred to in paragraph 1 and the expiry of the period referred to in paragraph 3, only the reporting Member State may request additional information from the sponsor concerning the aspects addressed in Part I of the assessment report, taking into account the considerations referred to in paragraph 5.

For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the third and fourth subparagraphs, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the reporting Member State which shall not exceed 12 days from receipt of the request.

Upon receipt of the additional information, the additional Member State concerned together with all other Member States concerned shall jointly review any additional information provided by the sponsor together with the original application and shall share any considerations relevant to the application. The coordinated review shall be performed within a maximum of 12 days from the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review. The reporting Member State shall take due account of the considerations of the Member States concerned and shall record how all such considerations have been dealt with.

Where the sponsor does not provide additional information within the period set by the reporting Member State in accordance with the third subparagraph, the application shall be deemed to have lapsed in the additional Member State concerned.

The request for additional information and the additional information shall be submitted through the EU portal.

7. The additional Member State concerned shall assess, for its territory, the aspects addressed in Part II of the assessment report within the period referred to in paragraph 3 and submit, through the EU portal, Part II of the assessment report, including its conclusion, to the sponsor. Within that period it may request, with justified reasons, additional information from the sponsor regarding aspects addressed in Part II of the assessment report as far as its territory is concerned.

8. For the purpose of obtaining and reviewing the additional information referred to in paragraph 7 from the sponsor in accordance with the second and third subparagraphs, the additional Member State concerned may extend the period referred to in paragraph 7 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the additional Member State concerned which shall not exceed 12 days from receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of 19 days.

Where the sponsor does not provide additional information within the period set by the additional Member State concerned in accordance with the second subparagraph, the application shall be deemed to have lapsed in the additional Member State concerned.

The request for additional information and the additional information shall be submitted through the EU portal.

9. Where, regarding the aspects covered by Part I of the assessment report, the conduct of the clinical trial is acceptable or acceptable subject to compliance with specific conditions, the additional Member State concerned shall include in its decision its conclusion on Part II of the assessment report.

10. The additional Member State concerned shall refuse to authorise the clinical trial if it disagrees with the conclusion of the reporting Member State as regards Part I of the assessment report on any of the grounds referred to in second subparagraph of paragraph 4, or if it finds, on duly justified grounds, that the aspects addressed in Part II of the assessment report are not complied with, or where an ethics committee has issued a negative opinion which, in accordance with the law of the additional Member State concerned, is valid for that entire additional Member State. That additional Member State concerned shall provide for an appeal procedure in respect of such refusal.

11. Where the additional Member State concerned has not notified the sponsor of its decision within the period referred to in paragraph 3, or in case that period has been extended in accordance with paragraph 6 or 8 where that additional Member State concerned has not notified the sponsor of its decision within the extended period, the conclusion on Part I of the assessment report shall be deemed to be the decision of that additional Member State concerned on the application for authorisation of the clinical trial.

12. A sponsor shall not submit an application dossier in accordance with this Article where a procedure set out in Chapter III is pending as regards that clinical trial.

CHAPTER III

AUTHORISATION PROCEDURE FOR A SUBSTANTIAL MODIFICATION OF A CLINICAL TRIAL

Article 15

General principles

A substantial modification, including the addition of a clinical trial site or the change of a principal investigator in the clinical trial site, may only be implemented if it has been approved in accordance with the procedure set out in this Chapter.

Article 16

Submission of application

In order to obtain an authorisation, the sponsor shall submit an application dossier to the Member States concerned through the EU portal.

Article 17

Validation of an application for the authorisation of a substantial modification of an aspect covered by Part I of the assessment report

1. The reporting Member State for the authorisation of a substantial modification shall be the reporting Member State for the initial authorisation procedure.

Member States concerned may communicate to the reporting Member State any considerations relevant to the validation of the application of a substantial modification within five days from the submission of the application dossier.

2. Within six days from the submission of the application dossier, the reporting Member State shall validate the application taking into account considerations expressed by the other Member States concerned and notify the sponsor through the EU portal as to whether:

- (a) the substantial modification concerns an aspect covered by Part I of the assessment report; and
- (b) the application dossier is complete in accordance with Annex II.

3. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 2, the substantial modification applied for shall be deemed to concern an aspect covered by Part I of the assessment report and the application dossier shall be deemed to be complete.

4. Where the reporting Member State, taking into account considerations expressed by the other Member States concerned, finds that the application does not concern an aspect covered by Part I of the assessment report or that the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a maximum of 10 days for the sponsor to comment on the application or to complete the application dossier through the EU portal.

Within five days from receipt of the comments or the completed application dossier, the reporting Member State shall notify the sponsor as to whether or not the application complies with the requirements set out in points (a) and (b) of paragraph 2.

Where the reporting Member State has not notified the sponsor within the period referred to in the second subparagraph, the substantial modification applied for shall be deemed to concern an aspect covered by Part I of the assessment report and the application dossier shall be deemed to be complete.

Where the sponsor has not provided comments or completed the application dossier within the period referred to in the first subparagraph, the application shall be deemed to have lapsed in all Member States concerned.

5. For the purposes of Articles 18, 19 and 22, the date on which the sponsor is notified in accordance with paragraph 2 or 4 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the respective periods referred to in paragraphs 2 and 4.

Article 18

Assessment of a substantial modification of an aspect covered by Part I of the assessment report

1. The reporting Member State shall assess the application with regard to an aspect covered by Part I of the assessment report, including whether the clinical trial will remain a low-intervention clinical trial after its substantial modification, and draw up an assessment report.

2. The assessment report shall contain one of the following conclusions concerning the aspects addressed in Part I of the assessment report:

- (a) the substantial modification is acceptable in view of the requirements set out in this Regulation;
- (b) the substantial modification is acceptable in view of the requirements set out in this Regulation, but subject to compliance with specific conditions which shall be specifically listed in that conclusion; or
- (c) the substantial modification is not acceptable in view of the requirements set out in this Regulation.

3. The reporting Member State shall submit, through the EU portal, the final assessment report including its conclusion, to the sponsor and to the other Member States concerned within 38 days from the validation date.

For the purposes of this Article and Articles 19 and 23, the reporting date shall be the date on which the final assessment report is submitted to the sponsor and to the other Member States concerned.

4. For clinical trials involving more than one Member State the assessment process of substantial modification shall include three phases:

- (a) an initial assessment phase performed by the reporting Member State within 19 days from the validation date;
- (b) a coordinated review phase performed within 12 days from the end of the initial assessment phase involving all Member States concerned; and
- (c) a consolidation phase performed by the reporting Member State within seven days from the end of coordinated review phase.

During the initial assessment phase, the reporting Member State shall develop a draft assessment report and circulate it to all Member States concerned.

During the coordinated review phase, all Member States concerned shall jointly review the application based on the draft assessment report and shall share any considerations relevant to the application.

During the consolidation phase, the reporting Member State shall take due account of the considerations of the other Member States concerned when finalising the assessment report and shall record how all such considerations have been dealt with. The reporting Member State shall submit the final assessment report to the sponsor and all other Member States concerned by the reporting date.

5. The reporting Member State may extend the period referred to in paragraph 3 by a further 50 days for clinical trials involving an advanced therapy investigational medicinal product or a medicinal product as set out in point 1 of the Annex to Regulation (EC) No 726/2004, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 4 and 6 of this Article shall apply *mutatis mutandis*.

6. Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph 4.

For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the third and fourth subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the reporting Member State which shall not exceed 12 days from receipt of the request.

Upon receipt of the additional information, the Member States concerned shall jointly review any additional information provided by the sponsor together with the original application and shall share any considerations relevant to the application. The coordinated review shall be performed within a maximum of 12 days from receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review. When finalising the assessment report, the reporting Member State shall take due account of the considerations of the other Member States concerned and shall record how all such considerations have been dealt with.

Where the sponsor does not provide additional information within the period determined by the reporting Member State in accordance with the third subparagraph, the application shall be deemed to have lapsed in all Member States concerned.

The request for additional information and the additional information shall be submitted through the EU portal.

Article 19

Decision on the substantial modification of an aspect covered by Part I of the assessment report

1. Each Member State concerned shall notify the sponsor through the EU portal as to whether the substantial modification is authorised, whether it is authorised subject to conditions, or whether authorisation is refused.

Notification shall be done by way of a single decision within five days from the reporting date.

An authorisation of a substantial modification subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

2. Where the conclusion of the reporting Member State is that the substantial modification is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State concerned.

Notwithstanding the first subparagraph, a Member State concerned may disagree with that conclusion of the reporting Member State only on the following grounds:

- (a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
- (b) infringement of its national law as referred to in Article 90;
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 4 or 6 of Article 18.

Where the Member State concerned disagrees with the conclusion on the basis of the second subparagraph, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States and to the sponsor.

A Member State concerned shall refuse to authorise a substantial modification if it disagrees with the conclusion of the reporting Member State as regards Part I of the assessment report on any of the grounds referred to in the second subparagraph, or where an ethics committee has issued a negative opinion which, in accordance with the law of that Member State concerned, is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

3. Where the conclusion of the reporting Member State, as regards the substantial modification of aspects covered by Part I of the assessment report, is that the substantial modification is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

4. Where the Member State concerned has not notified the sponsor of its decision within the period referred to in paragraph 1, the conclusion of the assessment report shall be deemed to be the decision of the Member State concerned on the application for authorisation of the substantial modification.

Article 20

Validation, assessment and decision regarding a substantial modification of an aspect covered by Part II of the assessment report

1. Within six days from the submission of the application dossier, the Member State concerned shall notify the sponsor through the EU portal of the following:

- (a) whether the substantial modification concerns an aspect covered by Part II of the assessment report; and
- (b) whether the application dossier is complete in accordance with Annex II.

2. Where the Member State concerned has not notified the sponsor within the period referred to in paragraph 1, the substantial modification applied for shall be deemed to concern an aspect covered by Part II of the assessment report and the application dossier shall be deemed to be complete.

3. Where the Member State concerned finds that the substantial modification does not concern an aspect covered by Part II of the assessment report or that the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a maximum of 10 days for the sponsor to comment on the application or to complete the application dossier through the EU portal.

Within five days from receipt of the comments or the completed application dossier, the reporting Member State shall notify the sponsor as to whether or not the application complies with the requirements set out in points (a) and (b) of paragraph 1.

Where the Member State concerned has not notified the sponsor within the period referred to in the second subparagraph, the substantial modification shall be deemed to concern an aspect covered by Part II of the assessment report and the application dossier shall be deemed to be complete.

Where the sponsor has not provided comments nor completed the application dossier within the period referred to in the first subparagraph, the application shall be deemed to have lapsed in the Member State concerned.

4. For the purpose of this Article, the date on which the sponsor is notified in accordance with paragraph 1 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the respective periods referred to in paragraphs 1 and 3.

5. The Member State concerned shall assess the application and shall submit to the sponsor, through the EU portal, Part II of the assessment report, including its conclusion, and the decision as to whether the substantial modification is authorised, whether it is authorised subject to conditions, or whether authorisation is refused.

Notification shall be done by way of a single decision within 38 days from the validation date.

An authorisation of a substantial modification subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

6. During the period referred to in the second subparagraph of paragraph 5, the Member State concerned may request, with justified reasons, additional information from the sponsor regarding the substantial modification as far as its territory is concerned.

For the purpose of obtaining and reviewing this additional information from the sponsor, the Member State concerned may extend the period referred to in the second subparagraph of paragraph 5 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the Member State concerned which shall not exceed 12 days from receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of 19 days.

Where the sponsor does not provide additional information within the period set by the Member State concerned in accordance with the third subparagraph, the application shall be deemed to have lapsed in that Member State.

The request for additional information and the additional information shall be submitted through the EU portal.

7. A Member State concerned shall refuse to authorise a substantial modification if it finds, on duly justified grounds, that the aspects covered by Part II of the assessment report are not complied with or where an ethics committee has issued a negative opinion which, in accordance with the law of that Member State concerned, is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

8. Where the Member State concerned has not notified the sponsor of its decision within the periods set out in paragraphs 5 and 6, the substantial modification shall be deemed to be authorised in that Member State.

Article 21

Substantial modification of aspects covered by Parts I and II of the assessment report

1. Where a substantial modification relates to aspects covered by Parts I and II of the assessment report, the application for authorisation of that substantial modification shall be validated in accordance with Article 17.

2. The aspects covered by Part I of the assessment report shall be assessed in accordance with Article 18 and the aspects covered by Part II of the assessment report shall be assessed in accordance with Article 22.

*Article 22***Assessment of a substantial modification of aspects covered by Parts I and II of the assessment report —
Assessment of the aspects covered by Part II of the assessment report**

1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 38 days from the validation date.
2. During the period referred to in paragraph 1, the Member State concerned may request, with justified reasons, additional information from the sponsor regarding this substantial modification as far as its territory is concerned.
3. For the purpose of obtaining and reviewing the additional information referred to in paragraph 2 from the sponsor in accordance with the third and fourth subparagraph, the Member State concerned may extend the period referred to in paragraph 1 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the Member State concerned which shall not exceed 12 days from the receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of 19 days.

Where the sponsor does not provide the requested additional information within the period set by the Member State concerned in accordance with the second subparagraph, the application shall be deemed to have lapsed in that Member State.

The request for additional information and the additional information shall be submitted through the EU portal.

*Article 23***Decision on the substantial modification of aspects covered by Parts I and II of the assessment report**

1. Each Member State concerned shall notify the sponsor through the EU portal as to whether the substantial modification is authorised, whether it is authorised subject to conditions, or whether authorisation is refused.

Notification shall be done by way of a single decision within five days from the reporting date or from the last day of the assessment period referred to in Article 22, whichever is later.

An authorisation of a substantial modification subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

2. Where the conclusion of the reporting Member State is that the substantial modification of aspects covered by Part I of the assessment report is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State concerned.

Notwithstanding the first subparagraph, a Member State concerned may disagree with the conclusion of the reporting Member State only on the following grounds:

- (a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
- (b) infringement of its national law as referred to in Article 90;
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 4 or 6 of Article 18.

Where the Member State concerned disagrees with the conclusion regarding the substantial modification of aspects covered by Part I of the assessment report on the basis of the second subparagraph, it shall communicate its disagreement, together with a detailed justification through the EU portal to the Commission, to all Member States, and to the sponsor.

3. Where, regarding the substantial modification of aspects covered by Part I of the assessment report, the substantial modification is acceptable or acceptable subject to compliance with specific conditions, the Member State concerned shall include in its decision its conclusion on the substantial modification of aspects covered by Part II of the assessment report.
4. A Member State concerned shall refuse to authorise a substantial modification if it disagrees with the conclusion of the reporting Member State as regards the substantial modification of aspects covered by Part I of the assessment report on any of the grounds referred to in second subparagraph of paragraph 2, or if it finds, on duly justified grounds, that the aspects covered by Part II of the assessment report are not complied with, or where an ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned, is valid for that entire Member State. That Member State concerned shall provide for an appeal procedure in respect of such refusal.
5. Where the conclusion of the reporting Member State as regards the substantial modification of aspects covered by Part I of the assessment report is that the substantial modification is not acceptable, that conclusion shall be deemed to be the conclusion of the Member State concerned.
6. Where the Member State concerned has not notified the sponsor of its decision within the periods referred to in paragraph 1, the conclusion on the substantial modification of aspects covered by Part I of the assessment report shall be deemed to be the decision of the Member State concerned on the application for authorisation of the substantial modification.

Article 24

Persons assessing the application for a substantial modification

Article 9 applies to assessments made under this Chapter.

CHAPTER IV

APPLICATION DOSSIER

Article 25

Data submitted in the application dossier

1. The application dossier for the authorisation of a clinical trial shall contain all required documentation and information necessary for the validation and assessment referred to in Chapter II and relating to:
 - (a) the conduct of the clinical trial, including the scientific context and arrangements taken,
 - (b) the sponsor, investigators, potential subjects, subjects, and clinical trial sites;
 - (c) the investigational medicinal products and, where necessary, the auxiliary medicinal products, in particular their properties, labelling, manufacturing and control;
 - (d) measures to protect subjects;
 - (e) justification as to why the clinical trial is a low-intervention clinical trial, in cases where this is claimed by the sponsor.

The list of required documentation and information is set out in Annex I.

2. The application dossier for the authorisation of a substantial modification shall contain all required documentation and information necessary for the validation and assessment referred to in Chapter III:
 - (a) a reference to the clinical trial or clinical trials which are substantially modified using the EU trial number referred to in the third subparagraph of Article 81(1) (the 'EU trial number');
 - (b) a clear description of the substantial modification, in particular, the nature of and the reasons for substantial modification;

- (c) a presentation of data and additional information in support of the substantial modification, where necessary;
- (d) a clear description of the consequences of the substantial modification as regards the rights and safety of the subject and the reliability and robustness of the data generated in the clinical trial.

The list of required documentation and information is set out in Annex II.

3. Non-clinical information submitted in an application dossier shall be based on data derived from studies complying with Union law on the principles of good laboratory practice, as applicable at the time of performance of those studies.
4. Where reference is made in the application dossier to data generated in a clinical trial, that clinical trial shall have been conducted in accordance with this Regulation or, if conducted prior to the date referred to in the second paragraph of Article 99, in accordance with Directive 2001/20/EC.
5. Where the clinical trial referred to in paragraph 4 has been conducted outside the Union, it shall have been conducted in accordance with principles equivalent to those of this Regulation as regards the rights and safety of the subject and the reliability and robustness of the data generated in the clinical trial.
6. Data from a clinical trial started as from the date referred to in the second paragraph of Article 99 shall only be submitted in an application dossier if that clinical trial has been registered prior to its start in a public register which is a primary or partner registry of, or a data provider to, the WHO ICTRP.

Data from a clinical trial started before the date referred to in the second paragraph of Article 99 shall only be submitted in an application dossier if that clinical trial is registered in a public register which is a primary or partner registry of, or a data provider to, the WHO ICTRP or if the results of that clinical trial have been published in an independent peer-reviewed scientific publication.

7. Data submitted in an application dossier which do not comply with paragraphs 3 to 6 shall not be considered in the assessment of an application for authorisation of a clinical trial or of a substantial modification.

Article 26

Language requirements

The language of the application dossier, or parts thereof, shall be determined by the Member State concerned.

Member States, in applying the first paragraph, shall consider accepting, for the documentation not addressed to the subject, a commonly understood language in the medical field.

Article 27

Update by way of delegated acts

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in respect of amending Annexes I and II in order to adapt them to technical progress or to take account of international regulatory developments in which the Union or the Member States are involved, in the field of clinical trials.

CHAPTER V

PROTECTION OF SUBJECTS AND INFORMED CONSENT

Article 28

General rules

1. A clinical trial may be conducted only where all of the following conditions are met:
 - (a) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
 - (b) the subjects, or where a subject is not able to give informed consent, his or her legally designated representative, have been informed in accordance with Article 29(2) to (6);

- (c) the subjects, or where a subject is not able to give informed consent, his or her legally designated representative, have given informed consent in accordance with Article 29(1), (7) and (8);
- (d) the rights of the subjects to physical and mental integrity, to privacy and to the protection of the data concerning them in accordance with Directive 95/46/EC are safeguarded;
- (e) the clinical trial has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects and both the risk threshold and the degree of distress are specifically defined in the protocol and constantly monitored;
- (f) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner;
- (g) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has been provided with the contact details of an entity where further information can be received in case of need;
- (h) no undue influence, including that of a financial nature, is exerted on subjects to participate in the clinical trial.

2. Without prejudice to Directive 95/46/EC, the sponsor may ask the subject or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject or his or her legally designated representative.

The scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection.

3. Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical trial at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

Article 29

Informed consent

1. Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document (or the record) by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the clinical trial.

2. Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:

- (a) enable the subject or his or her legally designated representative to understand:
 - (i) the nature, objectives, benefits, implications, risks and inconveniences of the clinical trial;
 - (ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification;
 - (iii) the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial; and
 - (iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical trial is discontinued;
- (b) be kept comprehensive, concise, clear, relevant, and understandable to a layperson;

- (c) be provided in a prior interview with a member of the investigating team who is appropriately qualified according to the law of the Member State concerned;
 - (d) include information about the applicable damage compensation system referred to in Article 76(1); and
 - (e) include the EU trial number and information about the availability of the clinical trial results in accordance with paragraph 6.
3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.
4. In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.
5. In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.
6. The subject shall be informed that the summary of the results of the clinical trial and a summary presented in terms understandable to a layperson will be made available in the EU database, referred to in Article 81 (the 'EU database'), pursuant to Article 37(4), irrespective of the outcome of the clinical trial, and, to the extent possible, when the summaries become available.
7. This Regulation is without prejudice to national law requiring that both the signature of the incapacitated person and the signature of his or her legally designated representative may be required on the informed consent form.
8. This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical trial.

Article 30

Informed consent in cluster trials

1. Where a clinical trial is to be conducted exclusively in one Member State, that Member State may, without prejudice to Article 35, and by way of derogation from points (b), (c), and (g) of Article 28(1), Article 29(1), point (c) of Article 29(2), Article 29(3), (4) and (5), points (a), (b) and (c) of Article 31(1) and points (a), (b) and (c) of Article 32(1), allow the investigator to obtain informed consent by the simplified means set out in paragraph 2 of this Article, provided that all of the conditions set out in paragraph 3 of this Article are fulfilled.
2. For clinical trials that fulfil the conditions set out in paragraph 3, informed consent shall be deemed to have been obtained if:
- (a) the information required under points (a), (b), (d) and (e) of Article 29(2) is given, in accordance with what is laid down in the protocol, prior to the inclusion of the subject in the clinical trial, and this information makes clear, in particular, that the subject can refuse to participate in, or withdraw at any time from, the clinical trial without any resulting detriment; and
 - (b) the potential subject, after being informed, does not object to participating in the clinical trial.
3. Informed consent may be obtained by the simplified means set out in paragraph 2, if all the following conditions are fulfilled:
- (a) the simplified means for obtaining informed consent do not contradict national law in the Member State concerned;
 - (b) the methodology of the clinical trial requires that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products in a clinical trial;
 - (c) the clinical trial is a low-intervention clinical trial and the investigational medicinal products are used in accordance with the terms of the marketing authorisation;

- (d) there are no interventions other than the standard treatment of the subjects concerned;
 - (e) the protocol justifies the reasons for obtaining informed consent with simplified means and describes the scope of information provided to the subjects, as well as the ways of providing information.
4. The investigator shall document all refusals and withdrawals and shall ensure that no data for the clinical trial are collected from subjects that refuse to participate in or have withdrawn from the clinical trial.

Article 31

Clinical trials on incapacitated subjects

1. In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical trial may be conducted only where, in addition to the conditions set out in Article 28, all of the following conditions are met:

- (a) the informed consent of their legally designated representative has been obtained;
- (b) the incapacitated subjects have received the information referred to in Article 29(2) in a way that is adequate in view of their capacity to understand it;
- (c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 29(2) to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator;
- (d) no incentives or financial inducements are given to the subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial;
- (e) the clinical trial is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical trials on persons able to give informed consent, or by other research methods;
- (f) the clinical trial relates directly to a medical condition from which the subject suffers;
- (g) there are scientific grounds for expecting that participation in the clinical trial will produce:
 - (i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved; or
 - (ii) some benefit for the population represented by the incapacitated subject concerned when the clinical trial relates directly to the life-threatening or debilitating medical condition from which the subject suffers and such trial will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the incapacitated subject's condition.

2. Point (g)(ii) of paragraph 1 shall be without prejudice to more stringent national rules prohibiting the conduct of those clinical trials on incapacitated subjects, where there are no scientific grounds to expect that participation in the clinical trial will produce a direct benefit to the subject outweighing the risks and burdens involved.

3. The subject shall as far as possible take part in the informed consent procedure.

Article 32

Clinical trials on minors

1. A clinical trial on minors may be conducted only where, in addition to the conditions set out in Article 28, all of the following conditions are met:

- (a) the informed consent of their legally designated representative has been obtained;
- (b) the minors have received the information referred to in Article 29(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

- (c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 29(2) to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator;
 - (d) no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial;
 - (e) the clinical trial is intended to investigate treatments for a medical condition that only occurs in minors or the clinical trial is essential with respect to minors to validate data obtained in clinical trials on persons able to give informed consent or by other research methods;
 - (f) the clinical trial either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
 - (g) there are scientific grounds for expecting that participation in the clinical trial will produce:
 - (i) a direct benefit for the minor concerned outweighing the risks and burdens involved; or
 - (ii) some benefit for the population represented by the minor concerned and such a clinical trial will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition.
2. The minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity.
3. If during a clinical trial the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical trial.

Article 33

Clinical trials on pregnant or breastfeeding women

A clinical trial on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 28, the following conditions are met:

- (a) the clinical trial has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved; or
- (b) if such clinical trial has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if:
 - (i) a clinical trial of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;
 - (ii) the clinical trial contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, foetuses or children; and
 - (iii) the clinical trial poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;
- (c) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child; and
- (d) no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial.

Article 34

Additional national measures

Member States may maintain additional measures regarding persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in clinical trials, or persons in residential care institutions.

*Article 35***Clinical trials in emergency situations**

1. By way of derogation from points (b) and (c) of Article 28(1), from points (a) and (b) of Article 31(1) and from points (a) and (b) of Article 32(1), informed consent to participate in a clinical trial may be obtained, and information on the clinical trial may be given, after the decision to include the subject in the clinical trial, provided that this decision is taken at the time of the first intervention on the subject, in accordance with the protocol for that clinical trial" and that all of the following conditions are fulfilled:

- (a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical trial;
- (b) there are scientific grounds to expect that participation of the subject in the clinical trial will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;
- (c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;
- (d) the investigator certifies that he or she is not aware of any objections to participate in the clinical trial previously expressed by the subject;
- (e) the clinical trial relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical trial is of such a nature that it may be conducted exclusively in emergency situations;
- (f) the clinical trial poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

2. Following an intervention pursuant to paragraph 1, informed consent in accordance with Article 29 shall be sought to continue the participation of the subject in the clinical trial, and information on the clinical trial shall be given, in accordance with the following requirements:

- (a) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 29(2) shall be given as soon as possible to the subject and to his or her legally designated representative;
- (b) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever is sooner and the information referred to in Article 29(2) shall be given as soon as possible to the the subject or his or her legally designated representative, whichever is sooner.

For the purposes of point (b), where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical trial shall be obtained from the subject as soon as he or she is capable of giving informed consent.

3. If the subject or, where applicable, his or her legally designated representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the clinical trial.

CHAPTER VI

START, END, TEMPORARY HALT, AND EARLY TERMINATION OF A CLINICAL TRIAL*Article 36***Notification of the start of a clinical trial and of the end of the recruitment of subjects**

1. The sponsor shall notify each Member State concerned of the start of a clinical trial in relation to that Member State through the EU portal.

That notification shall be made within 15 days from the start of the clinical trial in relation to that Member State.

2. The sponsor shall notify each Member State concerned of the first visit of the first subject in relation to that Member State through the EU portal.

That notification shall be made within 15 days from the first visit of the first subject in relation to that Member State.

3. The sponsor shall notify each Member State concerned of the end of the recruitment of subjects for a clinical trial in that Member State through the EU portal.

That notification shall be made within 15 days from the end of the recruitment of subjects. In case of re-start of recruitment, paragraph 1 shall apply.

Article 37

End of a clinical trial, temporary halt and early termination of a clinical trial and submission of the results

1. The sponsor shall notify each Member State concerned of the end of a clinical trial in relation to that Member State through the EU portal.

That notification shall be made within 15 days from the end of the clinical trial in relation to that Member State.

2. The sponsor shall notify each Member State concerned of the end of a clinical trial in all Member States concerned through the EU portal.

That notification shall be made within 15 days from the end of the clinical trial in the last Member State concerned.

3. The sponsor shall notify each Member State concerned of the end of a clinical trial in all Member States concerned and in all third countries in which the clinical trial has been conducted through the EU portal.

That notification shall be made within 15 days from the end of the clinical trial in the last of the Member States concerned and third countries in which the clinical trial has been conducted.

4. Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial. The content of that summary is set out in Annex IV.

It shall be accompanied by a summary written in a manner that is understandable to laypersons. The content of that summary is set out in Annex V.

However, where, for scientific reasons detailed in the protocol, it is not possible to submit a summary of the results within one year, the summary of results shall be submitted as soon as it is available. In this case, the protocol shall specify when the results are going to be submitted, together with a justification.

In addition to the summary of the results, where the clinical trial was intended to be used for obtaining a marketing authorisation for the investigational medicinal product, the applicant for marketing authorisation shall submit to the EU database the clinical study report within 30 days after the day the marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for marketing authorisation has withdrawn the application.

For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of those data.

5. The sponsor shall notify each Member State concerned of a temporary halt of a clinical trial in all Member States concerned for reasons not affecting the benefit-risk balance through the EU portal.

That notification shall be made within 15 days from the temporary halt of the clinical trial in all Member States concerned and shall include the reasons for such action.

6. When a temporarily halted clinical trial referred to in paragraph 5 is resumed the sponsor shall notify each Member State concerned through the EU portal.

That notification shall be made within 15 days from the restart of the temporarily halted clinical trial in all Member States concerned.

7. If a temporarily halted clinical trial is not resumed within two years, the expiry date of this period or the date of the decision of the sponsor not to resume the clinical trial, whichever is earlier, shall be deemed to be the date of the end of the clinical trial. In the case of early termination of the clinical trial, the date of the early termination shall be deemed to be the date of the end of the clinical trial.

In the case of early termination of the clinical trial for reasons not affecting the benefit-risk balance, the sponsor shall notify each Member State concerned through the EU portal of the reasons for such action and, when appropriate, follow-up measures for the subjects.

8. Without prejudice to paragraph 4, where the clinical trial protocol provides for an intermediate data analysis date prior to the end of the clinical trial, and the respective results of the clinical trial are available, a summary of those results shall be submitted to the EU database within one year of the intermediate data analysis date.

Article 38

Temporary halt or early termination by the sponsor for reasons of subject safety

1. For the purposes of this Regulation, the temporary halt or early termination of a clinical trial for reasons of a change of the benefit-risk balance shall be notified to the Member States concerned through the EU portal.

That notification shall be made without undue delay but not later than in 15 days of the date of the temporary halt or early termination. It shall include the reasons for such action and specify follow-up measures.

2. The restart of the clinical trial following a temporary halt as referred to in paragraph 1 shall be deemed to be a substantial modification subject to the authorisation procedure laid down in Chapter III.

Article 39

Update of the contents of the summary of results and summary for laypersons

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to amend Annexes IV and V, in order to adapt them to technical progress or to take account of international regulatory developments, in which the Union or the Member States are involved, in the field of clinical trials.

CHAPTER VII

SAFETY REPORTING IN THE CONTEXT OF A CLINICAL TRIAL

Article 40

Electronic database for safety reporting

1. The European Medicines Agency established by Regulation (EC) No 726/2004 (the 'Agency') shall set up and maintain an electronic database for the reporting provided for in Articles 42 and 43. That database shall be a module of the database referred to in Article 24 of Regulation (EC) No 726/2004 (the 'Eudravigilance database').

2. The Agency shall, in collaboration with Member States, develop a standard web-based structured form for the reporting by sponsors to the database referred to in paragraph 1 of suspected unexpected serious adverse reactions.

*Article 41***Reporting of adverse events and serious adverse events by the investigator to the sponsor**

1. The investigator shall record and document adverse events or laboratory abnormalities identified in the protocol as critical to the safety evaluation and report them to the sponsor in accordance with the reporting requirements and within the periods specified in the protocol.
2. The investigator shall record and document all adverse events, unless the protocol provides differently. The investigator shall report to the sponsor all serious adverse events occurring to subjects treated by him or her in the clinical trial, unless the protocol provides differently.

The investigator shall report serious adverse events to the sponsor without undue delay but not later than within 24 hours of obtaining knowledge of the events, unless, for certain serious adverse events, the protocol provides that no immediate reporting is required. Where relevant, the investigator shall send a follow-up report to the sponsor to allow the sponsor to assess whether the serious adverse event has an impact on the benefit-risk balance of the clinical trial.

3. The sponsor shall keep detailed records of all adverse events reported to it by the investigator.
4. If the investigator becomes aware of a serious adverse event with a suspected causal relationship to the investigational medicinal product that occurs after the end of the clinical trial in a subject treated by him or her, the investigator shall, without undue delay, report the serious adverse event to the sponsor.

*Article 42***Reporting of suspected unexpected serious adverse reactions by the sponsor to the Agency**

1. The sponsor of a clinical trial performed in at least one Member State shall report electronically and without delay to the database referred to in Article 40(1) all relevant information about the following suspected unexpected serious adverse reactions:
 - (a) all suspected unexpected serious adverse reactions to investigational medicinal products occurring in that clinical trial, irrespective of whether the suspected unexpected serious adverse reaction has occurred at a clinical trial site in the Union or in a third country;
 - (b) all suspected unexpected serious adverse reactions related to the same active substance, regardless of pharmaceutical form and strength or indication investigated, in investigational medicinal products used in the clinical trial, occurring in a clinical trial performed exclusively in a third country, if that clinical trial is sponsored:
 - (i) by that sponsor, or
 - (ii) by another sponsor who is either part of the same parent company as the sponsor of the clinical trial, or who develops a medicinal product jointly, on the basis of a formal agreement, with the sponsor of the clinical trial. For this purpose, provision of the investigational medicinal product or information to a future potential marketing authorisation holder on safety matters shall not be considered a joint development; and
 - (c) all suspected unexpected serious adverse reactions to investigational medicinal products occurring in any of the subjects of the clinical trial, which are identified by or come to the attention of the sponsor after the end of the clinical trial.
2. The period for the reporting of suspected unexpected serious adverse reactions by the sponsor to the Agency shall take account of the seriousness of the reaction and shall be as follows:
 - (a) in the case of fatal or life-threatening suspected unexpected serious adverse reactions, as soon as possible and in any event not later than seven days after the sponsor became aware of the reaction;
 - (b) in the case of non-fatal or non-life-threatening suspected unexpected serious adverse reactions, not later than 15 days after the sponsor became aware of the reaction;
 - (c) in the case of a suspected unexpected serious adverse reaction which was initially considered to be non-fatal or non-life threatening but which turns out to be fatal or life-threatening, as soon as possible and in any event not later than seven days after the sponsor became aware of the reaction being fatal or life-threatening.

Where necessary to ensure timely reporting, the sponsor may, in accordance with section 2.4 of Annex III, submit an initial incomplete report followed up by a complete report.

3. Where a sponsor, due to a lack of resources, does not have the possibility to report to the database referred to in Article 40(1) and the sponsor has the agreement of the Member State concerned, it may report to the Member State where the suspected unexpected serious adverse reaction occurred. That Member State shall report the suspected unexpected serious adverse reaction in accordance with paragraph 1 of this Article.

Article 43

Annual reporting by the sponsor to the Agency

1. Regarding investigational medicinal products other than placebo, the sponsor shall submit annually through the database referred to in Article 40(1) to the Agency a report on the safety of each investigational medicinal product used in a clinical trial for which it is the sponsor.
2. In the case of a clinical trial involving the use of more than one investigational medicinal product, the sponsor may, if provided for in the protocol, submit a single safety report on all investigational medicinal products used in that clinical trial.
3. The annual report referred to in paragraph 1 shall only contain aggregate and anonymised data.
4. The obligation referred to in paragraph 1 starts with the first authorisation of a clinical trial in accordance with this Regulation. It ends with the end of the last clinical trial conducted by the sponsor with the investigational medicinal product.

Article 44

Assessment by Member States

1. The Agency shall, by electronic means, forward to the Member States concerned the information reported in accordance with Article 42 and 43.
2. Member States shall cooperate in assessing the information reported in accordance with Articles 42 and 43. The Commission may, by means of implementing acts, set up and modify the rules on such cooperation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).
3. The responsible ethics committee shall be involved in the assessment of the information referred to in paragraphs 1 and 2, if it has been provided for in the law of the Member State concerned.

Article 45

Technical aspects

Technical aspects for safety reporting in accordance with Articles 41 to 44 are contained in Annex III. Where necessary in order to improve the level of protection of subjects, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to amend Annex III for any of the following purposes:

- (a) improving the information on the safety of medicinal products;
- (b) adapting technical requirements to technical progress;
- (c) taking account of international regulatory developments in the field of safety requirements in clinical trials, endorsed by bodies in which the Union or the Member States participate.

Article 46

Reporting with regard to auxiliary medicinal products

Safety reporting with regard to auxiliary medicinal products shall be made in accordance with Chapter 3 of Title IX of Directive 2001/83/EC.

CHAPTER VIII

CONDUCT OF A CLINICAL TRIAL, SUPERVISION BY THE SPONSOR, TRAINING AND EXPERIENCE, AUXILIARY MEDICINAL PRODUCTS*Article 47***Compliance with the protocol and good clinical practice**

The sponsor of a clinical trial and the investigator shall ensure that the clinical trial is conducted in accordance with the protocol and with the principles of good clinical practice.

Without prejudice to any other provision of Union law or Commission guidelines, the sponsor and the investigator, when drawing up the protocol and when applying this Regulation and the protocol, shall also take appropriate account of the quality standards and the ICH guidelines on good clinical practice.

The Commission shall make publicly available the detailed ICH guidelines on good clinical practice referred to in the second paragraph.

*Article 48***Monitoring**

In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical trial is in compliance with the requirements of this Regulation, the sponsor shall adequately monitor the conduct of a clinical trial. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the clinical trial, including the following characteristics:

- (a) whether the clinical trial is a low-intervention clinical trial;
- (b) the objective and methodology of the clinical trial; and
- (c) the degree of deviation of the intervention from normal clinical practice.

*Article 49***Suitability of individuals involved in conducting the clinical trial**

The investigator shall be a medical doctor as defined in national law, or a person following a profession which is recognised in the Member State concerned as qualifying for an investigator because of the necessary scientific knowledge and experience in patient care.

Other individuals involved in conducting a clinical trial shall be suitably qualified by education, training and experience to perform their tasks.

*Article 50***Suitability of clinical trial sites**

The facilities where the clinical trial is to be conducted shall be suitable for the conduct of the clinical trial in compliance with the requirements of this Regulation.

*Article 51***Traceability, storage, return and destruction of investigational medicinal products**

1. Investigational medicinal products shall be traceable. They shall be stored, returned and/or destroyed as appropriate and proportionate to ensure the safety of the subject and the reliability and robustness of the data generated in the clinical trial, in particular, taking into account whether the investigational medicinal product is an authorised investigational medicinal product, and whether the clinical trial is a low-intervention clinical trial.

The first subparagraph shall also apply to unauthorised auxiliary medicinal products.

2. The relevant information regarding the traceability, storage, return and destruction of medicinal products referred to in paragraph 1 shall be contained in the application dossier.

Article 52

Reporting of serious breaches

1. The sponsor shall notify the Member States concerned about a serious breach of this Regulation or of the version of the protocol applicable at the time of the breach through the EU portal without undue delay but not later than seven days of becoming aware of that breach.

2. For the purposes of this Article, a 'serious breach' means a breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial.

Article 53

Other reporting obligations relevant for subject safety

1. The sponsor shall notify the Member States concerned through the EU portal of all unexpected events which affect the benefit-risk balance of the clinical trial, but are not suspected unexpected serious adverse reactions as referred to in Article 42. That notification shall be made without undue delay but no later than 15 days from the date the sponsor became aware of this event.

2. The sponsor shall submit to the Member States concerned, through the EU portal, all inspection reports of third country authorities concerning the clinical trial. When requested by a Member State concerned, the sponsor shall submit a translation of the report or of its summary in an official language of the Union indicated in the request.

Article 54

Urgent safety measures

1. Where an unexpected event is likely to seriously affect the benefit-risk balance, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects.

2. The sponsor shall notify the Member States concerned, through the EU portal, of the event and the measures taken.

That notification shall be made without undue delay but no later than seven days from the date the measures have been taken.

3. This Article is without prejudice to Chapters III and VII.

Article 55

Investigator's brochure

1. The sponsor shall provide the investigator with the investigator's brochure.

2. The investigator's brochure shall be updated where new and relevant safety information becomes available, and shall be reviewed by the sponsor at least once per year.

*Article 56***Recording, processing, handling and storage of information**

1. All clinical trial information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
2. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves the transmission over a network.

*Article 57***Clinical trial master file**

The sponsor and the investigator shall keep a clinical trial master file. The clinical trial master file shall at all times contain the essential documents relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated, taking into account all characteristics of the clinical trial, including in particular whether the clinical trial is a low-intervention clinical trial. It shall be readily available, and directly accessible upon request, to the Member States.

The clinical trial master file kept by the investigator and that kept by the sponsor may have a different content if this is justified by the different nature of the responsibilities of the investigator and the sponsor.

*Article 58***Archiving of the clinical trial master file**

Unless other Union law requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical trial master file for at least 25 years after the end of the clinical trial. However, the medical files of subjects shall be archived in accordance with national law.

The content of the clinical trial master file shall be archived in a way that ensures that it is readily available and accessible, upon request, to the competent authorities.

Any transfer of ownership of the content of the clinical trial master file shall be documented. The new owner shall assume the responsibilities set out in this Article.

The sponsor shall appoint individuals within its organisation to be responsible for archives. Access to archives shall be restricted to those individuals.

The media used to archive the content of the clinical trial master file shall be such that the content remains complete and legible throughout the period referred to in the first paragraph.

Any alteration to the content of the clinical trial master file shall be traceable.

*Article 59***Auxiliary medicinal products**

1. Only authorised auxiliary medicinal products may be used in a clinical trial.
2. Paragraph 1 shall not apply where no authorised auxiliary medicinal product is available in the Union or where the sponsor cannot reasonably be expected to use an authorised auxiliary medicinal product. A justification to this effect shall be included in the protocol.

3. Member States shall ensure that unauthorised auxiliary medicinal products may enter their territories for the purpose of their use in a clinical trial in accordance with paragraph 2.

CHAPTER IX

MANUFACTURING AND IMPORT OF INVESTIGATIONAL MEDICINAL PRODUCTS AND AUXILIARY MEDICINAL PRODUCTS

Article 60

Scope of this Chapter

This Chapter shall apply to the manufacture and import of investigational medicinal products and auxiliary medicinal products.

Article 61

Authorisation of manufacturing and import

1. The manufacturing and import of investigational medicinal products in the Union shall be subject to the holding of an authorisation.
2. In order to obtain the authorisation referred to in paragraph 1, the applicant shall meet the following requirements:
 - (a) it shall have at its disposal, for manufacture or import, suitable and sufficient premises, technical equipment and control facilities complying with the requirements set out in this Regulation;
 - (b) it shall have permanently and continuously at its disposal the services of at least one qualified person who fulfils the conditions of qualification set out in Article 49(2) and (3) of Directive 2001/83/EC ('qualified person').
3. The applicant shall specify, in the application for authorisation, the types and pharmaceutical forms of the investigational medicinal product manufactured or imported, the manufacturing or import operations, the manufacturing process where relevant, the site where the investigational medicinal products are to be manufactured or the site in the Union to which they are to be imported, and detailed information concerning the qualified person.
4. Articles 42 to 45, and point (e) of Article 46 of Directive 2001/83/EC shall apply *mutatis mutandis* to the authorisation referred to in paragraph 1.
5. Paragraph 1 shall not apply to any of the following processes:
 - (a) re-labelling or re-packaging, where those processes are carried out in hospitals, health centres or clinics, by pharmacists or other persons legally authorised in the Member State concerned to carry out such processes, and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres or clinics taking part in the same clinical trial in the same Member State;
 - (b) preparation of radiopharmaceuticals used as diagnostic investigational medicinal products where this process is carried out in hospitals, health centres or clinics, by pharmacists or other persons legally authorised in the Member State concerned to carry out such process, and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres or clinics taking part in the same clinical trial in the same Member State;
 - (c) the preparation of medicinal products referred to in points (1) and (2) of Article 3 of Directive 2001/83/EC for use as investigational medicinal products, where this process is carried out in hospitals, health centres or clinics legally authorised in the Member State concerned to carry out such process and if the investigational medicinal products are intended to be used exclusively in hospitals, health centres or clinics taking part in the same clinical trial in the same Member State.
6. Member States shall make the processes set out in paragraph 5 subject to appropriate and proportionate requirements to ensure subject safety and reliability and robustness of the data generated in the clinical trial. They shall subject the processes to regular inspections.

*Article 62***Responsibilities of the qualified person**

1. The qualified person shall ensure that each batch of investigational medicinal products manufactured in or imported into the Union complies with the requirements set out in Article 63 and shall certify that those requirements are fulfilled.
2. The certification referred to in paragraph 1 shall be made available by the sponsor at the request of the Member State concerned.

*Article 63***Manufacturing and import**

1. Investigational medicinal products shall be manufactured by applying manufacturing practice which ensures the quality of such medicinal products in order to safeguard the safety of the subject and the reliability and robustness of clinical data generated in the clinical trial ('good manufacturing practice'). The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in order to specify the principles and guidelines of good manufacturing practice and the detailed arrangements for inspection for ensuring the quality of investigational medicinal products, taking account of subject safety or data reliability and robustness, technical progress and global regulatory developments in which the Union or the Member States are involved.

In addition, the Commission shall also adopt and publish detailed guidelines in line with those principles of good manufacturing practice and revise them when necessary in order to take account of technical and scientific progress.

2. Paragraph 1 shall not apply to the processes referred to in Article 61(5).
3. Investigational medicinal products imported into the Union shall be manufactured by applying quality standards at least equivalent to those laid down pursuant to paragraph 1.
4. The Member States shall ensure compliance with the requirements of this Article by means of inspections.

*Article 64***Modification of authorised investigational medicinal products**

Articles 61, 62 and 63 shall apply to authorised investigational medicinal products only as regards any modification of such products not covered by a marketing authorisation.

*Article 65***Manufacturing of auxiliary medicinal products**

Where the auxiliary medicinal product is not authorised, or where an authorised auxiliary medicinal product is modified while such modification is not covered by a marketing authorisation, it shall be manufactured according to the good manufacturing practice referred to in Article 63(1) or to at least an equivalent standard, in order to ensure appropriate quality.

CHAPTER X

LABELLING

*Article 66***Unauthorised investigational and unauthorised auxiliary medicinal products**

1. The following information shall appear on the outer packaging and on the immediate packaging of unauthorised investigational medicinal products and unauthorised auxiliary medicinal products:
 - (a) information to identify contact persons or persons involved in the clinical trial;
 - (b) information to identify the clinical trial;

- (c) information to identify the medicinal product;
- (d) information related to the use of the medicinal product.

2. The information which is to appear on the outer packaging and immediate packaging shall ensure subject safety and reliability and robustness of the data generated in the clinical trial, while taking account of the design of the clinical trial, whether the products are investigational or auxiliary medicinal product, and whether they are products with particular characteristics.

The information which is to appear on the outer packaging and immediate packaging shall be clearly legible.

A list of information which is to appear on the outer packaging and immediate packaging is set out in Annex VI.

Article 67

Authorised investigational and authorised auxiliary medicinal products

1. Authorised investigational medicinal products and authorised auxiliary medicinal products shall be labelled:

- (a) in accordance with Article 66(1); or
- (b) in accordance with Title V of Directive 2001/83/EC.

2. Notwithstanding point (b) of paragraph 1, where the specific circumstances, provided for in the protocol, of a clinical trial so require in order to ensure the safety of the subject or the reliability and robustness of data generated in a clinical trial, additional particulars relating to the identification of the clinical trial and of the contact person shall appear on the outer packaging and the immediate packaging of authorised investigational medicinal products. A list of these additional particulars appearing on the outer packaging and immediate packaging is set out in section C of Annex VI.

Article 68

Radiopharmaceuticals used as investigational medicinal products or as auxiliary medicinal products for a medical diagnosis

Articles 66 and 67 shall not apply to radiopharmaceuticals used as diagnostic investigational medicinal products or as diagnostic auxiliary medicinal products.

The products referred to in the first paragraph shall be labelled appropriately in order to ensure the safety of the subject and the reliability and robustness of data generated in the clinical trial.

Article 69

Language

The language of the information on the label shall be determined by the Member State concerned. The medicinal product may be labelled in several languages.

Article 70

Delegated act

The Commission shall be empowered to adopt delegated acts in accordance with Article 89 in respect of amending Annex VI in order to ensure subject safety and the reliability and robustness of data generated in a clinical trial or to take account of technical progress.

CHAPTER XI

SPONSOR AND INVESTIGATOR*Article 71***Sponsor**

A clinical trial may have one or several sponsors.

Any sponsor may delegate, in a written contract, any or all of its tasks to an individual, a company, an institution or an organisation. Such delegation shall be without prejudice to the responsibility of the sponsor, in particular regarding the safety of subjects and the reliability and robustness of the data generated in the clinical trial.

The investigator and the sponsor may be the same person.

*Article 72***Co-sponsorship**

1. Without prejudice to Article 74, where a clinical trial has more than one sponsor, all sponsors shall have the responsibilities of a sponsor set out in this Regulation, unless the sponsors decide otherwise in a written contract setting out their respective responsibilities. Where the contract does not specify to which sponsor a given responsibility is attributed, that responsibility shall lie with all sponsors.
2. By way of derogation from paragraph 1, the sponsors shall be jointly responsible for establishing:
 - (a) a sponsor responsible for compliance with the obligations of a sponsor in the authorisation procedures set out in Chapters II and III;
 - (b) a sponsor responsible for being a contact point for receiving all questions from subjects, investigators or any Member State concerned regarding the clinical trial and providing answers to them;
 - (c) a sponsor responsible for implementing the measures taken in accordance with Article 77.

*Article 73***Principal investigator**

A principal investigator shall ensure compliance of a clinical trial at a clinical trial site with the requirements of this Regulation.

The principal investigator shall assign tasks among the members of the team of investigators in a way which is not compromising the safety of subjects and the reliability and robustness of the data generated in the clinical trial at that clinical trial site.

*Article 74***Legal representative of the sponsor in the Union**

1. Where the sponsor of a clinical trial is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that legal representative shall be deemed to be a communication to the sponsor.
2. Member States may choose not to apply paragraph 1 as regards clinical trials to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that clinical trial who shall be the addressee for all communications with the sponsor provided for in this Regulation.

3. As regards clinical trials to be conducted in more than one Member State, all those Member States may choose not to apply paragraph 1 provided that they ensure that the sponsor establishes at least a contact person in the Union in respect of that clinical trial who shall be the addressee for all communications with the sponsor provided for in this Regulation.

Article 75

Liability

This Chapter shall not affect the civil and criminal liability of the sponsor, investigator, or persons to whom the sponsor has delegated tasks.

CHAPTER XII

DAMAGE COMPENSATION

Article 76

Damage compensation

1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical trial conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.
2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State concerned where the clinical trial is conducted.
3. Member States shall not require any additional use of the system referred to in paragraph 1 from the sponsor for low-intervention clinical trials, if any possible damage that could be suffered by a subject resulting from the use of the investigational medicinal product in accordance with the protocol of that specific clinical trial on the territory of that Member State is covered by the applicable compensation system already in place.

CHAPTER XIII

SUPERVISION BY MEMBER STATES, UNION INSPECTIONS AND CONTROLS

Article 77

Corrective measures to be taken by Member States

1. Where a Member State concerned has justified grounds for considering that the requirements set out in this Regulation are no longer met, it may take the following measures on its territory:
 - (a) revoke the authorisation of a clinical trial;
 - (b) suspend a clinical trial;
 - (c) require the sponsor to modify any aspect of the clinical trial.
2. Before the Member State concerned takes any of the measures referred to in paragraph 1 it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.
3. The Member State concerned shall immediately after taking a measure referred to in paragraph 1 inform all Member States concerned through the EU portal.
4. Each Member State concerned may consult the other Member States concerned before taking any of the measures referred to in paragraph 1.

*Article 78***Member State inspections**

1. Member States shall appoint inspectors to perform inspections in order to supervise compliance with this Regulation. They shall ensure that those inspectors are adequately qualified and trained.
2. Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.
3. Where a Member State concerned intends to carry out an inspection on its territory or in a third country with regard to one or several clinical trials which are conducted in more than one Member State concerned, it shall notify its intention to the other Member States concerned, the Commission and the Agency, through the EU portal, and shall inform them of its findings after the inspection.
4. Inspections fees, if any, may be waived for non-commercial sponsors.
5. In order to efficiently use the resources available and to avoid duplications, the Agency shall coordinate the cooperation between Member States concerned on inspections conducted in Member States, in third countries, and inspections conducted in the framework of an application for a marketing authorisation under Regulation (EC) No 726/2004.
6. Following an inspection, the Member State under whose responsibility the inspection has been conducted shall draw up an inspection report. That Member State shall make the inspection report available to the inspected entity and the sponsor of the relevant clinical trial and shall submit the inspection report through the EU portal.
7. The Commission shall specify, by means of implementing acts, the detailed arrangements for the inspection procedures including the qualification and training requirements for inspectors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).

*Article 79***Union controls**

1. The Commission may conduct controls in order to verify:
 - (a) whether Member States correctly supervise compliance with this Regulation;
 - (b) whether the regulatory system applicable to clinical trials conducted outside the Union ensures that point 8 of the Introduction and general principles contained in Annex I to Directive 2001/83/EC is complied with;
 - (c) whether the regulatory system applicable to clinical trials conducted outside the Union ensures that Article 25(5) of this Regulation is complied with.
2. The Union controls referred to in point (a) of paragraph 1 shall be organised in cooperation with the Member States concerned.

The Commission shall prepare in cooperation with the Member States a programme for the Union controls referred to in points (b) and (c) of paragraph 1.

The Commission shall report on the findings of each Union control carried out. Those reports shall, if appropriate, contain recommendations. The Commission shall submit those reports through the EU portal.

CHAPTER XIV

IT INFRASTRUCTURE*Article 80***EU portal**

The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a portal at Union level as a single entry point for the submission of data and information relating to clinical trials in accordance with this Regulation. The EU portal shall be technically advanced and user-friendly so as to avoid unnecessary work.

Data and information submitted through the EU portal shall be stored in the EU database.

Article 81

EU database

1. The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a EU database at Union level. The Agency shall be considered to be the controller of the EU database and shall be responsible for avoiding unnecessary duplication between the EU database and the EudraCT and Eudravigilance databases.

The EU database shall contain the data and information submitted in accordance with this Regulation.

The EU database shall identify each clinical trial by a unique EU trial number. The sponsor shall refer to this EU trial number in any subsequent submission relating or referring to that clinical trial.

2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also facilitate the communication between sponsors and Member States concerned and enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.

3. The EU database shall support the recording and submission to the Medicinal Product Dictionary, contained in the Eudravigilance database, of all the data on medicinal products without a marketing authorisation in the Union and substances not authorised as part of a medicinal product in the Union, that are necessary for the maintenance of that dictionary. To this effect and also with the purpose of enabling the sponsor to cross-refer to prior applications, an EU medicinal product number shall be issued for every medicinal product without a marketing authorisation and an EU active substances code shall be issued for each new active substance not previously authorised as part of a medicinal product in the Union. This shall be done before or during the application for authorisation of the first clinical trial with that product or active substance submitted in accordance with this Regulation. Those numbers shall be mentioned in all subsequent applications for clinical trials and for substantial modifications.

The data submitted, in accordance with the first subparagraph, describing medicinal products and substances shall comply with Union and international standards for the identification of medicinal products and active substances. When an investigational medicinal product which already has a marketing authorisation in the Union and/or an active substance which is part of a medicinal product with a marketing authorisation in the Union, is to be used in a clinical trial, the relevant product and active substance numbers shall be referred to in the application for that clinical trial.

4. The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:

- (a) protecting personal data in accordance with Regulation (EC) No 45/2001;
- (b) protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure;
- (c) protecting confidential communication between Member States in relation to the preparation of the assessment report;
- (d) ensuring effective supervision of the conduct of a clinical trial by Member States.

5. Without prejudice to paragraph 4, unless there is an overriding public interest in disclosure, data contained in the application dossier shall not be publicly accessible before the decision on the clinical trial has been made.

6. The EU database shall contain personal data only insofar as this is necessary for the purposes of paragraph 2.

7. No personal data of subjects shall be publicly accessible.

8. The user interface of the EU database shall be available in all official languages of the Union.
9. The sponsor shall permanently update in the EU database information on any changes to the clinical trials which are not substantial modifications but are relevant for the supervision of the clinical trial by the Member States concerned.
10. The Agency, the Commission and Member States shall ensure that the data subject may effectively exercise his or her rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and national data protection legislation implementing Directive 95/46/EC, respectively. They shall ensure that the data subject may effectively exercise the right of access to data relating to him or her, and the right to have inaccurate or incomplete data corrected or erased. Within their respective responsibilities, the Agency, the Commission and Member States shall ensure that inaccurate and unlawfully processed data are deleted, in accordance with the applicable law. Corrections and deletions shall be carried out as soon as possible, but no later than 60 days of a request being made by a data subject.

Article 82

Functionality of the EU portal and the EU database

1. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the EU portal and the EU database, together with the time frame for their implementation.
2. The Management Board of the Agency shall, on the basis of an independent audit report, inform the Commission when it has verified that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications drawn up pursuant to paragraph 1.
3. The Commission shall, when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the *Official Journal of the European Union*.

CHAPTER XV

COOPERATION BETWEEN MEMBER STATES

Article 83

National contact points

1. Each Member State shall designate one national contact point in order to facilitate the functioning of the procedures set out in Chapters II and III.
2. Each Member State shall communicate the contact point referred to in paragraph 1 to the Commission. The Commission shall publish a list of the national contact points.

Article 84

Support by the Agency and the Commission

The Agency shall support the functioning of the cooperation of the Member States in the framework of the authorisation procedures set out in Chapters II and III of this Regulation by maintaining and updating the EU portal and the EU database in accordance with the experience acquired during the implementation of this Regulation.

The Commission shall support the functioning of the cooperation of the Member States referred to in Article 44(2).

Article 85

Clinical Trials Coordination and Advisory Group

1. A Clinical Trials Coordination and Advisory Group (CTAG), composed of the national contact points referred to in Article 83 is hereby established.

2. The CTAG shall have the following tasks:
 - (a) to support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Regulation;
 - (b) to assist the Commission in providing the support referred to in the second paragraph of Article 84;
 - (c) to prepare recommendations on criteria regarding the selection of a reporting Member State.
3. The CTAG shall be chaired by a representative of the Commission.
4. The CTAG shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State. Any item of the agenda of the meeting shall be placed at the request of the Commission or a Member State.
5. The secretariat shall be provided by the Commission.
6. The CTAG shall draw up its rules of procedure. The rules of procedure shall be made public.

CHAPTER XVI

FEES

Article 86

General principle

This Regulation shall be without prejudice to the possibility for Member States to levy a fee for the activities set out in this Regulation, provided that the level of the fee is set in a transparent manner and on the basis of cost recovery principles. Member States may establish reduced fees for non-commercial clinical trials.

Article 87

One payment per activity per Member State

A Member State shall not require, for an assessment as referred to in Chapters II and III, multiple payments to different bodies involved in this assessment.

CHAPTER XVII

IMPLEMENTING ACTS AND DELEGATED ACTS

Article 88

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use established by Directive 2001/83/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.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 89

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Articles 27, 39, 45, 63(1) and 70 shall be conferred on the Commission for a period of five years from the date referred to in the second paragraph of Article 99. The Commission shall draw up a report in respect of the delegated powers not later than six months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Articles 27, 39, 45, 63(1) and 70 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 27, 39, 45, 63(1) and 70 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months from notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

CHAPTER XVIII

MISCELLANEOUS PROVISIONS

Article 90

Specific requirements for special groups of medicinal products

This Regulation shall not affect the application of national law prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from those cells, or of medicinal products used as abortifacients or of medicinal products containing narcotic substances within the meaning of the relevant international conventions in force such as the Single Convention on Narcotic Drugs of 1961 of the United Nations. The Member States shall communicate that national law to the Commission.

No gene therapy clinical trials may be carried out which result in modifications to the subject's germ line genetic identity.

Article 91

Relation with other Union legislation

This Regulation shall be without prejudice to Council Directive 97/43/Euratom ⁽¹⁾, Council Directive 96/29/Euratom ⁽²⁾, Directive 2001/18/EC of the European Parliament and of the Council ⁽³⁾, Directive 2004/23/EC of the European Parliament and of the Council ⁽⁴⁾, Directive 2002/98/EC of the European Parliament and of the Council ⁽⁵⁾, Directive 2010/53/EC of the European Parliament and of the Council ⁽⁶⁾, and Directive 2009/41/EC of the European Parliament and of the Council. ⁽⁷⁾

⁽¹⁾ Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).

⁽²⁾ Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L 159, 29.6.1996, p. 1).

⁽³⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽⁴⁾ Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

⁽⁵⁾ Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

⁽⁶⁾ Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).

⁽⁷⁾ Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

*Article 92***Investigational medicinal products, other products and procedures, free of charge for the subject**

Without prejudice to the Member States' competence for the definition of their health policy and for the organisation and delivery of health services and medical care, the costs for investigational medicinal products, auxiliary medicinal products, medical devices used for their administration and procedures specifically required by the protocol shall not be borne by the subject, unless the law of the Member State concerned provides otherwise.

*Article 93***Data protection**

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.
2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.

*Article 94***Penalties**

1. Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.
2. The rules referred to in paragraph 1 shall address, inter alia, the following:
 - (a) non-compliance with the provisions laid down in this Regulation on submission of information intended to be made publicly available to the EU database;
 - (b) non-compliance with the provisions laid down in this Regulation on subject safety.

*Article 95***Civil and criminal liability**

This Regulation is without prejudice to national and Union law on the civil and criminal liability of a sponsor or an investigator.

CHAPTER XIX

FINAL PROVISIONS*Article 96***Repeal**

1. Directive 2001/20/EC is repealed as from the date referred to in the second paragraph of Article 99.
2. References to Directive 2001/20/EC shall be construed as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex VII.

*Article 97***Review**

Five years after the date referred to in the second paragraph of Article 99, and every five years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation.

*Article 98***Transitional provision**

1. By way of derogation from Article 96(1) of this Regulation, where the request for authorisation of a clinical trial has been submitted before the date referred to in the second paragraph of Article 99 of this Regulation pursuant to Directive 2001/20/EC, that clinical trial shall continue to be governed by that Directive until three years from that date.
2. By way of derogation from Article 96(1) of this Regulation, where the request for authorisation of a clinical trial is submitted between six months after the date of publication of the notice referred to in Article 82(3) of this Regulation and 18 months after the date of publication of that notice, or, if the publication of that notice occurs earlier than 28 November 2015, where that request is submitted between 28 May 2016 and 28 May 2017, that clinical trial may be started in accordance with Articles 6, 7 and 9 of Directive 2001/20/EC. That clinical trial shall continue to be governed by that Directive until 42 months after the date of publication of the notice referred to in Article 82(3) of this Regulation, or, if that publication occurs earlier than 28 November 2015, until 28 May 2019.

*Article 99***Entry into force**

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

It shall apply as from six months after the publication of the notice referred to in Article 82(3), but in any event no earlier than 28 May 2016.

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

Done at Strasbourg, 16 April 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

ANNEX I

APPLICATION DOSSIER FOR THE INITIAL APPLICATION

A. INTRODUCTION AND GENERAL PRINCIPLES

1. The sponsor shall, where appropriate, refer to any previous applications. If these applications have been submitted by another sponsor, the written agreement from that sponsor shall be submitted.
2. Where a clinical trial has more than one sponsor, detailed information of the responsibilities of each of the sponsors shall be submitted in the application dossier.
3. The application shall be signed by the sponsor or a representative of the sponsor. This signature confirms that the sponsor is satisfied that:
 - (a) the information provided is complete;
 - (b) the attached documents contain an accurate account of the information available;
 - (c) the clinical trial is to be conducted in accordance with the protocol; and
 - (d) the clinical trial is to be conducted in accordance with this Regulation.
4. The application dossier for an application limited to Part I of the assessment report referred to in Article 11 shall be limited to sections B to J and Q of this Annex.
5. Without prejudice to Article 26, the application dossier for an application limited to Part II of the assessment report referred to in Article 11 and the application dossier for an application referred to in Article 14 shall be limited to sections K to R of this Annex.

B. COVER LETTER

6. The cover letter shall specify the EU trial number and the universal trial number and shall draw attention to any features which are particular to the clinical trial.
7. However, in the cover letter it is not necessary to reproduce information already contained in the EU application form, with the following exceptions:
 - (a) specific features of the clinical trial population, such as subjects not able to give informed consent, minors and pregnant or breastfeeding women;
 - (b) whether the clinical trial involves the first administration of a new active substance to humans;
 - (c) whether scientific advice relating to the clinical trial or the investigational medicinal product has been given by the Agency, a Member State or a third country;
 - (d) whether the clinical trial is part or is intended to be part of a Paediatric Investigation Plan (PIP) as referred to in Title II, Chapter 3, of Regulation (EC) No 1901/2006 (if the Agency has already issued a decision on the PIP, the cover letter contains the link to the decision of the Agency on its website);
 - (e) whether investigational medicinal products or auxiliary medicinal products are a narcotic, psychotropic or radiopharmaceutical;
 - (f) whether the investigational medicinal products consist of or contain a genetically-modified organism or organisms;
 - (g) whether the sponsor has obtained an orphan designation for the investigational medicinal product for an orphan condition;
 - (h) a comprehensive list, including the regulatory status, of all investigational medicinal products and a list of all auxiliary medicinal products; and

- (i) a list of medical devices which are to be investigated in the clinical trial but which are not part of the investigational medicinal product or products, together with a statement as to whether the medical devices are CE-marked for the intended use.
 8. The cover letter shall indicate where the information listed in paragraph 7 is contained in the application dossier.
 9. The cover letter shall indicate if the clinical trial is considered by the sponsor to be a low-intervention clinical trial and shall contain a detailed justification thereof.
 10. The cover letter shall indicate if the methodology of the clinical trial requires that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products in a clinical trial, and as a consequence whether informed consent will be obtained by simplified means.
 11. The cover letter shall indicate the location in the application dossier of the information necessary for assessing whether an adverse reaction is a suspected unexpected serious adverse reaction, that is the reference safety information.
 12. In the case of a resubmission, the cover letter shall specify the EU trial number for the previous clinical trial application, highlight the changes as compared to the previous submission and, if applicable, specify how any unresolved issues in the first submission have been addressed.
- C. EU APPLICATION FORM
13. The EU application form, duly completed.
- D. PROTOCOL
14. The protocol shall describe the objective, design, methodology, statistical considerations, purpose and organisation of the clinical trial.
 15. The protocol shall be identified by:
 - (a) the title of the clinical trial;
 - (b) the EU trial number;
 - (c) the sponsor's protocol code number specific for all versions of it (if relevant);
 - (d) the date and number of the version, to be updated when it is amended;
 - (e) a short title or name assigned to the protocol; and
 - (f) the name and address of the sponsor, as well as the name and function of the representative or representatives of the sponsor authorised to sign the protocol or any substantial modification to the protocol.
 16. The protocol shall, when possible, be written in an easily accessible and searchable format, rather than scanned images.
 17. The protocol shall at least include:
 - (a) a statement that the clinical trial is to be conducted in compliance with the protocol, with this Regulation and with the principles of good clinical practice;
 - (b) a comprehensive list of all investigational medicinal products and of all auxiliary medicinal products;
 - (c) a summary of findings from non-clinical studies that potentially have clinical significance and from other clinical trials that are relevant to the clinical trial;
 - (d) a summary of the known and potential risks and benefits including an evaluation of the anticipated benefits and risks to allow assessment in accordance with Article 6; for subjects in a clinical trial in an emergency situation, the scientific grounds for expecting that the participation of the subjects has the potential to produce a direct clinically relevant benefit shall be documented;
 - (e) where patients were involved in the design of the clinical trial, a description of their involvement;

- (f) a description of, and justification for, the dosage, the dosage regime, the route and mode of administration, and the treatment period for all investigational medicinal products and auxiliary medicinal products;
- (g) a statement of whether the investigational medicinal products and auxiliary medicinal products used in the clinical trial are authorised; if authorised, whether they are to be used in the clinical trial in accordance with the terms of their marketing authorisations, and, if not authorised, a justification for the use of non-authorised auxiliary medicinal products in the clinical trial;
- (h) a description of the groups and subgroups of the subjects participating in the clinical trial, including, where relevant, groups of subjects with specific needs, for example. age, gender, participation of healthy volunteers, subjects with rare and ultra rare diseases;
- (i) references to literature and data that are relevant to the clinical trial, and that provide background for the clinical trial;
- (j) a discussion of the relevance of the clinical trial in order to allow assessment in accordance with Article 6;
- (k) a description of the type of clinical trial to be conducted and a discussion of the trial design (including a schematic diagram of trial design, procedures and stages, if relevant);
- (l) a specification of the primary end-points and the secondary end-points, if any, to be measured during the clinical trial;
- (m) a description of the measures taken to minimise bias, including, if applicable, randomisation and blinding;
- (n) a description of the expected duration of subject participation and a description of the sequence and duration of all clinical trial periods, including follow-up, if relevant;
- (o) a clear and unambiguous definition of the end of the clinical trial in question and, if it is not the date of the last visit of the last subject, a specification of the estimated end date and a justification thereof;
- (p) a description of the criteria for discontinuing parts of the clinical trial or the entire clinical trial;
- (q) arrangements for the maintenance of clinical trial treatment randomisation codes and procedures for breaking codes, if relevant;
- (r) a description of procedures for the identification of data to be recorded directly on the Case Report Forms considered as source data;
- (s) a description of the arrangements to comply with the applicable rules for the collection, storage and future use of biological samples from clinical trial subjects, where applicable, unless contained in a separate document;
- (t) a description of the arrangements for tracing, storing, destroying and returning the investigational medicinal product and unauthorised auxiliary medicinal product in accordance with Article 51;
- (u) a description of the statistical methods to be employed, including, if relevant:
 - timing of any planned interim analysis and the number of subjects planned to be enrolled;
 - reasons for choice of sample size;
 - calculations of the power of the clinical trial and clinical relevance;
 - the level of significance to be used;
 - criteria for the termination of the clinical trial;
 - procedures for accounting for missing, unused, and spurious data and for reporting any deviation from the original statistical plan; and
 - the selection of subjects to be included in the analyses;

- (v) a description of the subject inclusion and exclusion criteria, including criteria for withdrawing individual subjects from treatment or from the clinical trial;
 - (w) a description of procedures relating to the withdrawal of subjects from treatment or from the clinical trial including procedures for the collection of data regarding withdrawn subjects, procedures for replacement of subjects and the follow-up of subjects that have withdrawn from treatment or from the clinical trial;
 - (x) a justification for including subjects who are incapable of giving informed consent or other special populations, such as minors;
 - (y) a justification for the gender and age allocation of subjects and, if a specific gender or age group is excluded from or underrepresented in the clinical trials, an explanation of the reasons and justification for these exclusion criteria;
 - (z) a detailed description of the recruitment and informed consent procedure, especially when subjects are incapable of giving informed consent;
 - (aa) a description of the treatments, including medicinal products, which are permitted or not permitted, before or during the clinical trial;
 - (ab) a description of the accountability procedures for the supply and administration of medicinal products to subjects including the maintenance of blinding, if applicable;
 - (ac) a description of procedures for monitoring subject compliance, if applicable;
 - (ad) a description of arrangements for monitoring the conduct of the clinical trial;
 - (ae) a description of the arrangements for taking care of the subjects after their participation in the clinical trial has ended, where such additional care is necessary because of the subjects' participation in the clinical trial and where it differs from that normally expected for the medical condition in question;
 - (af) a specification of the efficacy and safety parameters as well as the methods and timing for assessing, recording, and analysing these parameters;
 - (ag) a description of ethical considerations relating to the clinical trial if those have not been described elsewhere;
 - (ah) a statement from the sponsor (either in the protocol or in a separate document) confirming that the investigators and institutions involved in the clinical trial are to permit clinical trial-related monitoring, audits and regulatory inspections, including provision of direct access to source data and documents;
 - (ai) a description of the publication policy;
 - (aj) duly substantiated reasons for the submission of the summary of the results of the clinical trials after more than one year;
 - (ak) a description of the arrangements to comply with the applicable rules on the protection of personal data; in particular organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;
 - (al) a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects;
 - (am) a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.
18. If a clinical trial is conducted with an active substance available in the Union under different trade names in a number of authorised medicinal products, the protocol may define the treatment in terms of the active substance or Anatomical Therapeutic Chemical (ATC) code (level 3-5) only and not specify the trade name of each product.

19. With regard to the notification of adverse events, the protocol shall identify the categories of:
 - (a) adverse events or laboratory anomalies that are critical to safety evaluations and must be reported by the investigator to the sponsor, and
 - (b) serious adverse events which do not require immediate reporting by the investigator to the sponsor.
 20. The protocol shall describe the procedures for:
 - (a) eliciting and recording adverse events by the investigator, and the reporting of relevant adverse events by the investigator to the sponsor;
 - (b) reporting by the investigator to the sponsor of those serious adverse events which have been identified in the protocol as not requiring immediate reporting;
 - (c) reporting of suspected unexpected serious adverse reactions by the sponsor to the Eudravigilance database; and
 - (d) follow-up of subjects after adverse reactions including the type and duration of follow-up.
 21. In case the sponsor intends to submit a single safety report on all investigational medicinal products used in the clinical trial in accordance with Article 43(2), the protocol shall indicate the reasons thereof.
 22. Issues regarding labelling and the unblinding of investigational medicinal products shall be addressed in the protocol, where necessary.
 23. The protocol shall be accompanied by the Charter of the Data Safety Monitoring Committee, if applicable.
 24. The protocol shall be accompanied by a synopsis of the protocol.
- E. INVESTIGATOR'S BROCHURE (IB)
25. An IB, which has been prepared in accordance with the state of scientific knowledge and international guidance, shall be submitted.
 26. The purpose of the IB is to provide the investigators and others involved in the clinical trial with information to facilitate their understanding of the rationale for, and their compliance with, key features of the protocol, such as the dose, dose frequency/interval, methods of administration, and safety monitoring procedures.
 27. The information in the IB shall be presented in a concise, simple, objective, balanced and non-promotional form that enables a clinician or investigator to understand it and make an unbiased risk-benefit assessment of the appropriateness of the proposed clinical trial. It shall be prepared from all available information and evidence that supports the rationale for the proposed clinical trial and the safe use of the investigational medicinal product in the clinical trial and be presented in the form of summaries.
 28. If the investigational medicinal product is authorised, and is used in accordance with the terms of the marketing authorisation, the approved summary of product characteristics (SmPC) shall be the IB. If the conditions of use in the clinical trial differ from those authorised, the SmPC shall be supplemented with a summary of relevant non-clinical and clinical data that support the use of the investigational medicinal product in the clinical trial. Where the investigational medicinal product is identified in the protocol only by its active substance, the sponsor shall select one SmPC as equivalent to the IB for all medicinal products that contain that active substance and are used at any clinical trial site.
 29. For a multinational clinical trial where the medicinal product to be used in each Member State concerned is authorised at national level, and the SmPC varies among Member States concerned, the sponsor shall choose one SmPC for the whole clinical trial. This SmPC shall be the one best suited to ensure patient safety.

30. If the IB is not an SmPC, it shall contain a clearly identifiable section called the 'Reference Safety Information' (RSI). In accordance with paragraphs 10 and 11 of Annex III, the RSI shall contain product information on the investigational medicinal product and on how to determine what adverse reactions are to be considered as expected adverse reactions, and on the frequency and nature of those adverse reactions.

F. DOCUMENTATION RELATING TO COMPLIANCE WITH GOOD MANUFACTURING PRACTICE (GMP) FOR THE INVESTIGATIONAL MEDICINAL PRODUCT

31. As regards documentation relating to GMP compliance, the following shall apply.

32. No documentation needs to be submitted where the investigational medicinal product is authorised and is not modified, whether or not it is manufactured in the Union.

33. If the investigational medicinal product is not authorised, and does not have a marketing authorisation from a third country that is party to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and is not manufactured in the Union, the following documentation shall be submitted:

(a) a copy of the authorisation referred to in Article 61; and

(b) certification by the qualified person in the Union that the manufacturing complies with GMP at least equivalent to the GMP in the Union, unless there are specific arrangements provided for in mutual recognition agreements between the Union and third countries.

34. In all other cases, a copy of the authorisation referred to in Article 61 shall be submitted.

35. For processes related to investigational medicinal products set out in Article 61(5), which are not subject to an authorisation in accordance with Article 61, documentation to demonstrate compliance with the requirements referred to in Article 61(6) shall be submitted.

G. INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD)

36. The IMPD shall give information on the quality of any investigational medicinal product, the manufacture and control of the investigational medicinal product, and data from non-clinical studies and from its clinical use.

1.1. **Data relating to the investigational medicinal product**

Introduction

37. Regarding data, the IMPD may be replaced by other documentation which may be submitted alone or with a simplified IMPD. The details of this 'simplified IMPD' are set out in section 1.2 'Simplified IMPD by referring to other documentation'.

38. Each section of the IMPD shall be prefaced with a detailed table of contents and a glossary of terms.

39. The information in the IMPD shall be concise. The IMPD must not be unnecessarily voluminous. It is preferable to present data in tabular form accompanied by a brief narrative highlighting the main salient points.

Quality data

40. Quality data shall be submitted in a logical structure such as that of Module 3 of the ICH Common Technical Document format.

Non-clinical pharmacology and toxicology data

41. The IMPD shall also contain summaries of non-clinical pharmacology and toxicology data for any investigational medicinal product used in the clinical trial in accordance with international guidance. It shall contain a reference list of studies conducted and appropriate literature references. Wherever appropriate, it is preferable to present data in tabular form accompanied by a brief narrative highlighting the main salient points. The summaries of the studies conducted shall allow an assessment of the adequacy of the study and whether the study has been conducted according to an acceptable protocol.

42. Non-clinical pharmacology and toxicology data shall be submitted in a logical structure, such as that of Module 4 of the ICH Common Technical Document format.
43. The IMPD shall provide a critical analysis of the data, including justification for omissions of data, and an assessment of the safety of the product in the context of the proposed clinical trial rather than a mere factual summary of the studies conducted.
44. The IMPD shall contain a statement of the good laboratory practice status or equivalent standards, as referred to in Article 25(3).
45. The test material used in toxicity studies shall be representative of that of the clinical trial use in terms of qualitative and quantitative impurity profiles. The preparation of the test material shall be subject to the controls necessary to ensure this and thus support the validity of the study.

Data from previous clinical trials and human experience

46. Data from previous clinical trials and human experience shall be submitted in a logical structure, such as that of Module 5 of the ICH Common Technical Document format.
47. This section shall provide summaries of all available data from previous clinical trials and human experience with the investigational medicinal products.

It shall also contain a statement of the compliance with good clinical practice of those previous clinical trials, as well as a reference to the public entry referred to in Article 25(6).

Overall risk and benefit assessment

48. This section shall provide a brief integrated summary that critically analyses the non-clinical and clinical data in relation to the potential risks and benefits of the investigational medicinal product in the proposed clinical trial unless this information is already provided in the protocol. In the latter case, it shall cross-refer to the relevant section in the protocol. The text shall identify any studies that were terminated prematurely and discuss the reasons. Any evaluation of foreseeable risks and anticipated benefits for studies on minors or incapacitated adults shall take account of the specific provisions set out in this Regulation.
49. Where appropriate, safety margins shall be discussed in terms of relative systemic exposure to the investigational medicinal product, preferably based on 'area under the curve' (AUC) data, or peak concentration (C_{max}) data, whichever is considered more relevant, rather than in terms of applied dose. The clinical relevance of any findings in the non-clinical and clinical studies along with any recommendations for further monitoring of effects and safety in the clinical trials shall also be discussed.

1.2. Simplified IMPD by referring to other documentation

50. The applicant may refer to other documentation submitted alone or with a simplified IMPD.

Possibility of referring to the IB

51. The applicant may either provide a stand-alone IMPD or cross-refer to the IB for the reference safety information and the summaries of pre-clinical and clinical parts of the IMPD. In the latter case, the summaries of pre-clinical information and clinical information shall include data, preferably in tables, providing sufficient detail to allow assessors to reach a decision on the potential toxicity of the investigational medicinal product and the safety of its use in the proposed clinical trial. If there is some special aspect of the pre-clinical data or clinical data that requires a detailed expert explanation or discussion beyond what would usually be included in the IB, the pre-clinical and clinical information shall be submitted as part of the IMPD.

Possibility of referring to the SmPC

52. The applicant may submit the version of the SmPC valid at the time of application, as the IMPD if the investigational medicinal product is authorised. The exact requirements are detailed in Table 1. Where new data are provided, it should be clearly identified.

Table 1: Content of the simplified IMPD

Types of previous assessment	Quality data	Non-clinical data	Clinical data
The investigational medicinal product is authorised or has a marketing authorisation in an ICH country and is used in the clinical trial:			
— within the conditions of the SmPC	SmPC		
— outside the conditions of the SmPC	SmPC	If appropriate	If appropriate
— after modification (for example blinding)	P+A	SmPC	SmPC
Another pharmaceutical form or strength of the investigational medicinal product is authorised or has a marketing authorisation in an ICH country and the investigational medicinal product is supplied by the marketing authorisation holder	SmPC+P+A	Yes	Yes
The investigational medicinal product is not authorised and has no marketing authorisation in an ICH country but the active substance is contained in an authorised medicinal product, and			
— is supplied by the same manufacturer	SmPC+P+A	Yes	Yes
— is supplied by another manufacturer	SmPC+S+P+A	Yes	Yes
The investigational medicinal product was subject to a previous clinical trial application and authorised in the Member State concerned and has not been modified, and			
— no new data are available since last amendment to the clinical trial application,	Reference to previous submission		
— new data are available since last amendment to the clinical trial application,	New data	New data	New data
— is used under different conditions	If appropriate	If appropriate	If appropriate

(S: Data relating to the active substance; P: Data relating to the investigational medicinal product; A: Additional information on Facilities and Equipment, Adventitious Agents Safety Evaluation, Novel Excipients, and Solvents for Reconstitution and Diluents)

53. If the investigational medicinal product is defined in the protocol in terms of active substance or ATC code (see above, paragraph 18), the applicant may replace the IMPD by one representative SmPC for each active substance/active substance pertaining to that ATC group. Alternatively, the applicant may provide a collated document containing information equivalent to that in the representative SmPCs for each active substance that could be used as an investigational medicinal product in the clinical trial.

1.3. IMPD in cases of placebo

54. If the investigational medicinal product is a placebo, the information requirements shall be limited to quality data. No additional documentation is required if the placebo has the same composition as the tested investigational medicinal product (with the exception of the active substance), is manufactured by the same manufacturer, and is not sterile.

H. AUXILIARY MEDICINAL PRODUCT DOSSIER

55. Without prejudice to Article 65, the documentation requirements set out in sections F and G shall also apply to auxiliary medicinal products. However, where the auxiliary medicinal product is authorised in the Member State concerned, no additional information is required.

I. SCIENTIFIC ADVICE AND PAEDIATRIC INVESTIGATION PLAN (PIP)

56. If available, a copy of the summary of scientific advice of the Agency, or of any Member State or third country, with regard to the clinical trial shall be submitted.
57. If the clinical trial is part of an agreed PIP, a copy of the Agency's decision on the agreement on the PIP, and the opinion of the Paediatric Committee, unless these documents are fully accessible via the internet shall be submitted. In the latter case, a link to this documentation in the cover letter is sufficient (see section B).

J. CONTENT OF THE LABELLING OF THE INVESTIGATIONAL MEDICINAL PRODUCTS

58. A description of the content of the labelling of the investigational medicinal product in accordance with Annex VI shall be provided.

K. RECRUITMENT ARRANGEMENTS (INFORMATION PER MEMBER STATE CONCERNED)

59. Unless described in the protocol, a separate document shall describe in detail the procedures for inclusion of subjects and shall provide a clear indication of what the first act of recruitment is.
60. Where the recruitment of subjects is done through advertisement, copies of the advertising material shall be submitted, including any printed materials, and audio or visual recordings. The procedures proposed for handling responses to the advertisement shall be outlined. This includes copies of communications used to invite subjects to participate in the clinical trial and arrangements for information or advice to the respondents found not to be suitable for inclusion in the clinical trial.

L. SUBJECT INFORMATION, INFORMED CONSENT FORM AND INFORMED CONSENT PROCEDURE (INFORMATION PER MEMBER STATE CONCERNED)

61. All information given to the subjects (or, where applicable, to their legally designated representatives) before their decision to participate or abstain from participation shall be submitted together with the form for written informed consent, or other alternative means according to Article 29(1) for recording informed consent.
62. A description of procedures relating to informed consent for all subjects, and in particular:
- (a) in clinical trials with minors or incapacitated subjects, the procedures to obtain informed consent from the legally designated representatives, and the involvement of the minor or incapacitated subject shall be described;
 - (b) if a procedure with consent witnessed by an impartial witness is to be used, relevant information on the reason for using an impartial witness, on the selection of the impartial witness and on the procedure for obtaining informed consent shall be provided;
 - (c) in the case of clinical trials in emergency situations as referred to in Article 35, the procedure for obtaining the informed consent of the subject or the legally designated representative to continue the clinical trial shall be described;
 - (d) in the case of clinical trials in emergency situations as referred to in Article 35, the description of the procedures followed to identify the urgency of the situation and to document it;
 - (e) in the case of clinical trials where their methodology requires that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products, as referred to in Article 30, and where, as a consequence, simplified means for obtaining informed consent will be used, the simplified means shall be described.
63. In the cases set out in paragraph 62, the information given to the subject and to his or her legally designated representative shall be submitted.

M. SUITABILITY OF THE INVESTIGATOR (INFORMATION PER MEMBER STATE CONCERNED)

64. A list of the planned clinical trial sites, the name and position of the principal investigators and the planned number of subjects at the sites shall be submitted.
65. Description of the qualification of the investigators in a current curriculum vitae and other relevant documents shall be submitted. Any previous training in the principles of good clinical practice or experience obtained from work with clinical trials and patient care shall be described.
66. Any conditions, such as economic interests and institutional affiliations, that might influence the impartiality of the investigators shall be presented.

N. SUITABILITY OF THE FACILITIES (INFORMATION PER MEMBER STATE CONCERNED)

67. A duly justified written statement on the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product and including a description of the suitability of facilities, equipment, human resources and description of expertise, issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned, shall be submitted.

O. PROOF OF INSURANCE COVER OR INDEMNIFICATION (INFORMATION PER MEMBER STATE CONCERNED)

68. Proof of insurance, a guarantee, or a similar arrangement shall be submitted, if applicable.

P. FINANCIAL AND OTHER ARRANGEMENTS (INFORMATION PER MEMBER STATE CONCERNED)

69. A brief description of the financing of the clinical trial.
70. Information on financial transactions and compensation paid to subjects and investigator/site for participating in the clinical trial shall be submitted.
71. Description of any other agreement between the sponsor and the site shall be submitted.

Q. PROOF OF PAYMENT OF FEE (INFORMATION PER MEMBER STATE CONCERNED)

72. Proof of payment shall be submitted, if applicable.

R. PROOF THAT DATA WILL BE PROCESSED IN COMPLIANCE WITH UNION LAW ON DATA PROTECTION

73. A statement by the sponsor or his or her representative that data will be collected and processed in accordance with Directive 95/46/EEC shall be provided.

ANNEX II

APPLICATION DOSSIER FOR SUBSTANTIAL MODIFICATION

A. INTRODUCTION AND GENERAL PRINCIPLES

1. Where a substantial modification concerns more than one clinical trial of the same sponsor and the same investigational medicinal product, the sponsor may make a single request for authorisation of the substantial modification. The cover letter shall contain a list of all clinical trials to which the application for substantial modification relates, with the EU trial numbers and respective modification code numbers of each of those clinical trials.
2. The application shall be signed by the sponsor or a representative of the sponsor. This signature shall confirm that the sponsor is satisfied that:
 - (a) the information provided is complete;
 - (b) the attached documents contain an accurate account of the information available; and
 - (c) the clinical trial will be conducted in accordance with the amended documentation.

B. COVER LETTER

3. A cover letter with the following information:
 - (a) in its subject line, the EU trial number with the title of the clinical trial and the substantial modification code number which allows unique identification of the substantial modification, and which shall be used consistently throughout the application dossier;
 - (b) identification of the applicant;
 - (c) identification of the substantial modification (the sponsor's substantial modification code number and date), whereby the modification may refer to several changes in the protocol or scientific supporting documents;
 - (d) a highlighted indication of any special issues relating to the modification and an indication as to where the relevant information or text is located in the original application dossier;
 - (e) identification of any information not contained in the modification application form that might impact on the risk to subjects; and
 - (f) where applicable, a list of all clinical trials which are substantially modified, with EU trial numbers and respective modification code numbers.

C. MODIFICATION APPLICATION FORM

4. The modification application form, duly completed.

D. DESCRIPTION OF THE MODIFICATION

5. The modification shall be presented and described as follows:
 - (a) an extract from the documents to be amended showing previous and new wording in track changes, as well as an extract showing only the new wording, and a explanation of the changes; and
 - (b) notwithstanding point (a), if the changes are so widespread or far-reaching that they justify an entirely new version of the document, a new version of the entire document (in such cases, an additional table lists the amendments to the documents, whereby identical changes can be grouped).
6. The new version of the document shall be identified by the date and an updated version number.

E. SUPPORTING INFORMATION

7. Where applicable, additional supporting information shall at least include:
 - (a) summaries of data;
 - (b) an updated overall risk/benefit assessment;

- (c) possible consequences for subjects already included in the clinical trial;
- (d) possible consequences for the evaluation of the results;
- (e) documents which relate to any changes to the information provided to subjects or their legally designated representatives, the informed consent procedure, informed consent forms, information sheets, or to letters of invitation; and
- (f) a justification for the changes sought in the application for a substantial modification.

F. UPDATE OF EU APPLICATION FORM

8. If a substantial modification involves changes to entries on the EU application form referred to in Annex I, a revised version of that form shall be submitted. The fields affected by the substantial modification shall be highlighted in the revised form.

G. PROOF OF PAYMENT OF FEE (INFORMATION PER MEMBER STATE CONCERNED)

9. Proof of payment shall be submitted, if applicable.
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ANNEX III

SAFETY REPORTING

1. REPORTING OF SERIOUS ADVERSE EVENTS BY THE INVESTIGATOR TO THE SPONSOR

1. The investigator does not need to actively monitor subjects for adverse events once the clinical trial has ended with regard to the subjects treated by him, unless otherwise provided for in the protocol.

2. REPORTING OF SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTIONS (SUSARS) BY THE SPONSOR TO THE AGENCY IN ACCORDANCE WITH ARTICLE 42

2.1. **Adverse Events and Causality**

2. Medication errors, pregnancies and uses outside what is foreseen in the protocol, including misuse and abuse of the product, shall be subject to the same obligation to report as adverse reactions.
3. In determining whether an adverse event is an adverse reaction, consideration shall be given to whether there is a reasonable possibility of establishing a causal relationship between the event and the investigational medicinal product based on an analysis of available evidence.
4. In the absence of information on causality provided by the reporting investigator, the sponsor shall consult the reporting investigator and encourage him to express an opinion on this issue. The causality assessment given by the investigator shall not be downgraded by the sponsor. If the sponsor disagrees with the investigator's causality assessment, the opinion of both the investigator and the sponsor shall be provided with the report.

2.2. **Expectedness, unexpectedness and the RSI**

5. In determining whether an adverse event is unexpected, consideration shall be given to whether the event adds significant information on the specificity, increase of occurrence, or severity of a known, already documented serious adverse reaction.
6. The expectedness of an adverse reaction shall be set out by the sponsor in the RSI. Expectedness shall be determined on the basis of events previously observed with the active substance and not on the basis of the anticipated pharmacological properties of a medicinal product or events related to the subject's disease.
7. The RSI shall be contained in the SmPC or the IB. The covering letter shall refer to the location of the RSI in the application dossier. If the investigational medicinal product is authorised in several Member States concerned with different SmPCs, the sponsor shall select the most appropriate SmPC, with reference to subject safety, as the RSI.
8. The RSI may change during the conduct of a clinical trial. For the purpose of reporting SUSARs the version of the RSI at the moment of occurrence of the SUSARs shall apply. Thus, a change of the RSI impacts on the number of adverse reactions to be reported as SUSARs. Regarding the applicable RSI for the purpose of the annual safety report, see section 3 of this Annex.
9. If information on expectedness has been provided by the reporting investigator, this shall be taken into consideration by the sponsor.

2.3. **Information for the reporting of SUSARs**

10. The information shall at least include:
 - (a) a valid EU trial number;
 - (b) a sponsor study number;
 - (c) an identifiable coded subject;
 - (d) an identifiable reporter;
 - (e) a SUSAR;
 - (f) a suspect investigational medicinal product (including active substance name-code);
 - (g) a causality assessment.

11. In addition, in order to properly process the report electronically, the following administrative information shall be provided:
 - (a) the sender's (case) safety report unique identifier;
 - (b) the receive date of the initial information from the primary source;
 - (c) the receipt date of the most recent information;
 - (d) the worldwide unique case identification number;
 - (e) the sender identifier.

2.4. Follow-up reports of SUSARs

12. If the initial report of a SUSAR referred to in point (a) of Article 42(2) (fatal or life-threatening) is incomplete, for example if the sponsor has not provided all the information within seven days, the sponsor shall submit a completed report based on the initial information within an additional eight days.
13. The clock for initial reporting (day 0 = Di 0) starts as soon as the information containing the minimum reporting criteria has been received by the sponsor.
14. If significant new information on an already reported case is received by the sponsor, the clock starts again at day zero, that is the date of receipt of the new information. This information shall be reported as a follow-up report within 15 days.
15. If the initial report of a SUSAR referred to in Article 42(2)(c) (initially considered to be non-fatal or non-life-threatening but which turns out to be fatal or life-threatening) is incomplete, a follow-up report shall be made as soon as possible, but within a maximum of seven days of first knowledge of the reaction being fatal or life-threatening. The sponsor shall submit a completed report within an additional eight days.
16. In cases where a SUSAR turns out to be fatal or life-threatening, whereas initially it was considered as non-fatal or not life-threatening, if the initial report has not yet been submitted, a combined report shall be created.

2.5. Unblinding treatment allocation

17. The investigator shall only unblind the treatment allocation of a subject in the course of a clinical trial if unblinding is relevant to the safety of the subject.
18. When reporting a SUSAR to the Agency, the sponsor shall only unblind the treatment allocation of the affected subject to whom the SUSAR relates.
19. If an event is potentially a SUSAR the blind shall be broken for that subject only by the sponsor. The blind shall be maintained for other persons responsible for the ongoing conduct of the clinical trial (such as the management, monitors, investigators) and those persons responsible for data analysis and interpretation of results at the conclusion of the clinical trial, such as biometrics personnel.
20. Unblinded information shall be accessible only to persons who need to be involved in the safety reporting to the Agency, to Data Safety Monitoring Boards ('DSMB'), or to persons performing ongoing safety evaluations during the clinical trial.
21. However, for clinical trials carried out in high morbidity or high mortality disease, where efficacy end-points could also be SUSARs or when mortality or another 'serious' outcome, that may potentially be reported as a SUSAR, is the efficacy end-point in a clinical trial, the integrity of the clinical trial may be compromised if the blind is systematically broken. Under these and similar circumstances, the sponsor shall highlight in the protocol which serious events are to be treated as disease-related and are not subject to systematic unblinding and expedited reporting.
22. If following unblinding, an event turns out to be a SUSAR the reporting rules for SUSARs set out in Article 42 and in Section 2 of this Annex shall apply.

3. ANNUAL SAFETY REPORTING BY THE SPONSOR

23. The report shall contain, in an appendix, the RSI in effect at the start of the reporting period.

24. The RSI in effect at the start of the reporting period shall serve as RSI during the reporting period.
 25. If there are significant changes to the RSI during the reporting period they shall be listed in the annual safety report. Moreover, in this case the revised RSI shall be submitted as an appendix to the report, in addition to the RSI in effect at the start of the reporting period. Despite the change to the RSI, the RSI in effect at the start of the reporting period serves as RSI during the reporting period.
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ANNEX IV

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL

The summary of the results of the clinical trial shall contain information on the following elements:

A. CLINICAL TRIAL INFORMATION:

1. Clinical trial identification (including title of the trial and protocol number);
2. Identifiers (including EU trial number, other identifiers);
3. Sponsor details (including scientific and public contact points);
4. Paediatric regulatory details (including information whether the clinical trial is a part of a Paediatric Investigation Plan);
5. Result analysis stage (including information about intermediate data analysis date, interim or final analysis stage, date of global end of the clinical trial). For clinical trials replicating studies on already authorised investigational medicinal products and used in accordance with the terms of the marketing authorisation, the summary of the results should also indicate identified concerns in the overall results of the clinical trial relating to relevant aspects of the efficacy of the related medicinal product;
6. General information about the clinical trial (including information about main objectives of the trial, trial design, scientific background and explanation of rationale for the trial; date of the start of the trial, measures of protection of subjects taken, background therapy; and statistical methods used);
7. Population of subjects (including information with actual number of subjects included in the clinical trial in the Member State concerned, in the Union and in third countries; age group breakdown, gender breakdown).

B. SUBJECT DISPOSITION:

1. Recruitment (including information on the number of subjects screened, recruited and withdrawn; inclusion and exclusion criteria; randomisation and blinding details; investigational medicinal products used);
2. Pre-assignment Period;
3. Post Assignment Periods.

C. BASELINE CHARACTERISTICS:

1. Baseline Characteristics (Required) Age;
2. Baseline Characteristics (Required) Gender;
3. Baseline Characteristics (Optional) Study Specific Characteristic.

D. END POINTS:

1. End point definitions (*)
2. End Point #1
Statistical Analyses
3. End Point #2
Statistical Analyses

(*) Information shall be provided for as many end points as defined in the protocol.

E. ADVERSE EVENTS:

1. Adverse events information;
2. Adverse event reporting group;
3. Serious adverse event;
4. Non-serious adverse event.

F. ADDITIONAL INFORMATION:

1. Global Substantial Modifications;
 2. Global Interruptions and re-starts;
 3. Limitations, addressing sources of potential bias and imprecisions and Caveats;
 4. A declaration by the submitting party on the accuracy of the submitted information.
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ANNEX V

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL FOR LAYPERSONS

The summary of the results of the clinical trial for laypersons shall contain information on the following elements:

1. Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers);
 2. Name and contact details of the sponsor;
 3. General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it);
 4. Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria);
 5. Investigational medicinal products used;
 6. Description of adverse reactions and their frequency;
 7. Overall results of the clinical trial;
 8. Comments on the outcome of the clinical trial;
 9. Indication if follow up clinical trials are foreseen;
 10. Indication where additional information could be found.
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ANNEX VI

LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS AND AUXILIARY MEDICINAL PRODUCTS

A. UNAUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

A.1. **General rules**

1. The following particulars shall appear on the immediate and the outer packaging:
 - (a) name, address and telephone number of the main contact for information on the product, clinical trial and emergency unblinding; this may be the sponsor, contract research organisation or investigator (for the purpose of this Annex this is referred to as the 'main contact');
 - (b) the name of the substance and its strength or potency, and in the case of blind clinical trials the name of the substance is to appear with the name of the comparator or placebo on the packaging of both the unauthorised investigational medicinal product and the comparator or placebo;
 - (c) pharmaceutical form, route of administration, quantity of dosage units;
 - (d) the batch or code number identifying the contents and packaging operation;
 - (e) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
 - (f) the subject identification number and/or the treatment number and, where relevant, the visit number;
 - (g) the name of the investigator (if not included in (a) or (e));
 - (h) directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);
 - (i) 'For clinical trial use only' or similar wording;
 - (j) the storage conditions;
 - (k) period of use (expiry date or re-test date as applicable), in month and year format and in a manner that avoids any ambiguity; and
 - (l) 'Keep out of reach of children', except when the product is for use in trials where the product is not taken home by subjects.
2. Symbols or pictograms may be included to clarify certain information mentioned above. Additional information, warnings or handling instructions may be displayed.
3. The address and telephone number of the main contact shall not be required to appear on the label if subjects have been given a leaflet or card which provides these details and have been instructed to keep this in their possession at all times.

A.2. **Limited labelling of immediate packaging**A.2.1. *Immediate and outer packaging provided together*

4. When the product is provided to the subject or the person administering the medicinal product in an immediate packaging and outer packaging intended to remain together, and the outer packaging carries the particulars listed in section A.1., the following particulars shall appear on the immediate packaging (or any sealed dosing device that contains the immediate package):
 - (a) name of the main contact;
 - (b) pharmaceutical form, route of administration (may be excluded for oral solid dose forms), quantity of dosage units and, in the case of clinical trials which do not involve the blinding of the label, the name/identifier and strength/potency;
 - (c) batch and/or code number identifying the contents and packaging operation;

- (d) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
- (e) the subject identification number and/or the treatment number and, where relevant, the visit number; and
- (f) period of use (expiry date or re-test date as applicable), in month and year format and in a manner that avoids any ambiguity.

A.2.2. *Small immediate packaging*

5. If the immediate packaging takes the form of blister packs or small units such as ampoules on which the particulars required in section A.1. cannot be displayed, the outer packaging provided shall bear a label with those particulars. The immediate packaging shall contain the following:

- (a) name of the main contact;
- (b) route of administration (may be excluded for oral solid dose forms) and, in the case of clinical trials which do not involve the blinding of the label, the name/identifier and strength/potency;
- (c) batch or code number identifying the contents and packaging operation;
- (d) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
- (e) the subject identification number/treatment number and, where relevant, the visit number; and
- (f) period of use (expiry date or re-test date as applicable), in month and year format and in a manner that avoids any ambiguity.

B. UNAUTHORISED AUXILIARY MEDICINAL PRODUCTS

6. The following particulars shall appear on the immediate and the outer packaging:

- (a) name of the main contact;
- (b) name of the medicinal product, followed by its strength and pharmaceutical form;
- (c) statement of the active substances expressed qualitatively and quantitatively per dosage unit;
- (d) batch or code number identifying the contents and packaging operation;
- (e) clinical trial reference code allowing identification of the clinical trial site, investigator and subject;
- (f) directions for use (reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product);
- (g) 'For clinical trial use only' or similar wording;
- (h) the storage conditions; and
- (i) period of use (expiry date or retest date as applicable).

C. ADDITIONAL LABELLING FOR AUTHORISED INVESTIGATIONAL MEDICINAL PRODUCTS

7. In accordance with Article 67(2), the following particulars shall appear on the immediate and the outer packaging:

- (a) name of the main contact;
- (b) clinical trial reference code allowing identification of the clinical trial site, investigator, sponsor and subject;
- (c) 'For clinical trial use only' or similar wording.

D. REPLACING OF INFORMATION

8. The particulars listed in sections A, B and C, other than those particulars listed in paragraph 9, may be omitted from the label of a product and made available by other means, for example by use of a centralised electronic randomisation system, use of a centralised information system, provided that the safety of the subject and the reliability and robustness of data are not compromised. This shall be justified in the protocol.

9. The particulars referred to in the following points shall not be omitted from the label of a product:
- (a) paragraph 1, points (b), (c), (d), (f), (j) and (k);
 - (b) paragraph 4, points (b), (c), (e), and (f);
 - (c) paragraph 5, points (b), (c), (e), and (f);
 - (d) paragraph 6, points (b), (d), (e), (h), and (i).
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ANNEX VII

CORRELATION TABLE

Directive 2001/20/EC	This Regulation
Article 1(1)	Article 1 and Article 2(1) and (2) points (1), (2) and (4)
Article 1(2)	Article 2(2) point (30)
Article 1(3), first subparagraph	—
Article 1(3), second subparagraph	Article 47, third subparagraph
Article 1(4)	Article 47, second subparagraph
Article 2	Article 2
Article 3(1)	—
Article 3(2)	Articles 4, 28, 29 and 76
Article 3(3)	Article 28(1)(f)
Article 3(4)	Article 28(1)(g)
Article 4	Articles 10(1), 28, 29 and 32
Article 5	Articles 10(2), 28, 29 and 31
Article 6	Articles 4 to 14
Article 7	Articles 4 to 14
Article 8	—
Article 9	Articles 4 to 14
Article 10(a)	Articles 15 to 24
Article 10(b)	Article 54
Article 10(c)	Articles 37 and 38
Article 11	Article 81
Article 12	Article 77
Article 13(1)	Article 61(1) to (4)
Article 13(2)	Article 61(2)
Article 13(3), first subparagraph	Articles 62(1) and 63(1) and (3)
Article 13(3), second subparagraph	Article 63(1)
Article 13(3), third subparagraph	—
Article 13(4)	Article 62
Article 13(5)	—
Article 14	Articles 66 to 70
Article 15(1)	Article 78(1), (2) and (5)
Article 15(2)	Article 78(6)

Directive 2001/20/EC	This Regulation
Article 15(3)	—
Article 15(4)	—
Article 15(5)	Articles 57, 58 and 78(7)
Article 16	Article 41
Article 17(1)(a) to (c)	Article 42
Article 17(1)(d)	—
Article 17(2)	Article 43
Article 17(3)(a)	—
Article 17(3)(b)	Article 44(1)
Article 18	—
Article 19, first paragraph, first sentence	Article 75
Article 19, first paragraph, second sentence	Article 74
Article 19, second paragraph	Article 92
Article 19, third paragraph	—
Article 20	—
Article 21	Article 88
Article 22	—
Article 23	—
Article 24	—

REGULATION (EU) No 537/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on specific requirements regarding statutory audit of public-interest entities and repealing
Commission Decision 2005/909/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Statutory auditors and audit firms are entrusted by law to conduct statutory audits of public-interest entities with a view to enhancing the degree of confidence of the public in the annual and consolidated financial statements of such entities. The public-interest function of statutory audit means that a broad community of people and institutions rely on the quality of a statutory auditor's or an audit firm's work. Good audit quality contributes to the orderly functioning of markets by enhancing the integrity and efficiency of financial statements. Thus, statutory auditors fulfil a particularly important societal role.
- (2) Union legislation requires that the financial statements, comprising annual financial statements or consolidated financial statements, of credit institutions, insurance undertakings, issuers of securities admitted to trading on a regulated market, payment institutions, undertakings for collective investment in transferable securities (UCITS), electronic money institutions and alternative investment funds be audited by one or more persons entitled to carry out such audits in accordance with Union law, namely: Article 1(1) of Council Directive 86/635/EEC ⁽³⁾, Article 1(1) of Council Directive 91/674/EEC ⁽⁴⁾, Article 4(4) of Directive 2004/109/EC of the European Parliament and of the Council ⁽⁵⁾, Article 15(2) of Directive 2007/64/EC of the European Parliament and of the Council ⁽⁶⁾, Article 73 of Directive 2009/65/EC of the European Parliament and of the Council ⁽⁷⁾, Article 3(1) of

⁽¹⁾ OJ C 191, 29.6.2012, p. 61.

⁽²⁾ Position of the European Parliament of 3 April 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

⁽³⁾ Council Directive 86/635/EEC of 8 December 1986 on the annual accounts and consolidated accounts of banks and other financial institutions (OJ L 372, 31.12.1986, p. 1).

⁽⁴⁾ Council Directive 91/674/EEC of 19 December 1991 on the annual accounts and consolidated accounts of insurance undertakings (OJ L 374, 31.12.1991, p. 7).

⁽⁵⁾ 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 and amending Directive 2001/34/EC (OJ L 390, 31.12.2004, p. 38).

⁽⁶⁾ Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 5.12.2007, p. 1).

⁽⁷⁾ 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) (OJ L 302, 17.11.2009, p. 32).

Directive 2009/110/EC of the European Parliament and of the Council ⁽¹⁾, and Article 22(3) of Directive 2011/61/EU of the European Parliament and of the Council ⁽²⁾. Moreover, point (1) of Article 4(1) of Directive 2004/39/EC of the European Parliament and of the Council ⁽³⁾ also requires that the annual financial statements of investment firms be audited when Directive 2013/34/EU of the European Parliament and of the Council ⁽⁴⁾ is not applicable.

- (3) The conditions for the approval of the persons responsible for carrying out the statutory audit as well as the minimum requirements for carrying out such statutory audit are laid down in Directive 2006/43/EC of the European Parliament and of the Council ⁽⁵⁾.
- (4) On 13 October 2010 the Commission published a Green Paper entitled 'Audit Policy: Lessons from the Crisis', which launched a wide public consultation, in the general context of financial market regulatory reform, on the role and scope of audit and how the audit function could be enhanced in order to contribute to increased financial stability. That public consultation showed that the rules of Directive 2006/43/EC regarding the carrying out of the statutory audit of annual and consolidated financial statements of public-interest entities could be improved. The European Parliament issued an own-initiative report on the Green Paper on 13 September 2011. The European Economic and Social Committee also adopted a report on that Green Paper on 16 June 2011.
- (5) It is important to lay down detailed rules with a view to ensuring that the statutory audits of public-interest entities are of adequate quality and are carried out by statutory auditors and audit firms subject to stringent requirements. A common regulatory approach should enhance the integrity, independence, objectivity, responsibility, transparency and reliability of statutory auditors and audit firms carrying out statutory audits of public-interest entities, contributing to the quality of statutory audits in the Union, thus to the smooth functioning of the internal market, while achieving a high level of consumer and investor protection. The development of a separate act for public-interest entities should also ensure consistent harmonisation and uniform application of the rules and thus contribute to a more effective functioning of the internal market. These strict requirements should be applicable to statutory auditors and audit firms only insofar as they carry out statutory audits of public-interest entities.
- (6) The statutory audit of cooperatives and savings banks is characterised in some Member States by a system that does not allow them to choose their statutory auditor or audit firm freely. The audit association to which the cooperative or savings bank belongs as a member is obliged by law to carry out the statutory audit. Such audit associations act on a non-profit-making basis without pursuing commercial interests, as results from their legal nature. In addition, the organisational units of these associations are not associated with a common economic interest, which could jeopardise their independence. Accordingly, Member States should have the possibility to exempt cooperatives within the meaning of point (14) of Article 2 of Directive 2006/43/EC, savings banks or similar entities as referred to in Article 45 of Directive 86/635/EEC or their subsidiaries or legal successors from this Regulation provided that the principles of independence laid down in Directive 2006/43/EC are complied with.

⁽¹⁾ Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009 on the taking up, pursuit and prudential supervision of the business of electronic money institutions amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC (OJ L 267, 10.10.2009, p. 7).

⁽²⁾ 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 (OJ L 174, 1.7.2011, p. 1).

⁽³⁾ Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC (OJ L 145, 30.4.2004, p. 1).

⁽⁴⁾ Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013 on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings, amending Directive 2006/43/EC of the European Parliament and of the Council and repealing Council Directives 78/660/EEC and 83/349/EEC (OJ L 182, 29.6.2013, p. 19).

⁽⁵⁾ 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, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

- (7) The level of fees received from one audited entity and the structure of fees can threaten the independence of a statutory auditor or an audit firm. Thus, it is important to ensure that audit fees are not based on any form of contingency and that, when the audit fees from a single client including its subsidiaries are significant, a specific procedure involving the audit committee is established to secure the quality of the audit. If the statutory auditor or the audit firm becomes excessively dependent on a single client, the audit committee should decide on the basis of proper grounds whether the statutory auditor or the audit firm may continue to carry out the statutory audit. When taking such decision, the audit committee should take into consideration, inter alia, the threats to independence and the consequences of such decision.
- (8) The provision of certain services other than statutory audit (non-audit services) to audited entities by statutory auditors, audit firms or members of their networks may compromise their independence. Therefore, it is appropriate to prohibit the provision of certain non-audit services such as specific tax, consultancy and advisory services to the audited entity, to its parent undertaking and to its controlled undertakings within the Union. The services that involve playing any part in the management or decision-making of the audited entity might include working capital management, providing financial information, business process optimisation, cash management, transfer pricing, creating supply chain efficiency and the like. Services linked to the financing, capital structure and allocation, and investment strategy of the audited entity should be prohibited except the provision of services such as due diligence services, issuing comfort letters in connection with prospectuses issued by the audited entity and other assurance services.
- (9) It should be possible for Member States to decide to allow the statutory auditors and the audit firms to provide certain tax and valuation services when such services are immaterial or have no direct effect, separately or in the aggregate, on the audited financial statements. Where such services involve aggressive tax planning, they should not be considered as immaterial. Accordingly, a statutory auditor or an audit firm should not provide such services to the audited entity. A statutory auditor or an audit firm should be able to provide non-audit services which are not prohibited under this Regulation, if the provision of those services has been approved in advance by the audit committee and if the statutory auditor or the audit firm has satisfied itself that provision of those services does not pose a threat to the independence of the statutory auditor or the audit firm that cannot be reduced to an acceptable level by the application of safeguards.
- (10) With a view to avoiding conflicts of interest it is important that the statutory auditor or the audit firm, before accepting or continuing an engagement for a statutory audit of a public-interest entity, assess whether the independence requirements are met, and in particular whether any threats to independence arise as a result of the relationship with that entity. The statutory auditor or the audit firm should confirm its independence annually to the audit committee of the audited entity and should discuss with that committee any threat to its independence as well as the safeguards applied to mitigate those threats.
- (11) Directive 95/46/EC of the European Parliament and of the Council ⁽¹⁾ should govern the processing of personal data carried out in the Member States in the context of this Regulation and such processing of personal data should be subject to the supervision of the Member States' competent authorities, in particular the public independent authorities designated by the Member States. Any exchange or transmission of information by competent authorities should comply with the rules on the transfer of personal data as laid down in Directive 95/46/EC.
- (12) A sound engagement quality control review of the work carried out in each statutory audit engagement should be conducive to high audit quality. Therefore, the statutory auditor or the audit firm should not issue his, her or its audit report until such an engagement quality control review has been completed.
- (13) The results of the statutory audit of a public-interest entity should be presented to the stakeholders in the audit report. In order to increase the confidence of stakeholders in the financial statements of the audited entity, it is particularly important that the audit report be well-founded and solidly substantiated. In addition to the information required to be provided under Article 28 of Directive 2006/43/EC, the audit report should in particular include sufficient information on the independence of the statutory auditor or the audit firm and on whether the statutory audit was considered capable of detecting irregularities, including fraud.

⁽¹⁾ 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 (OJ L 281, 23.11.1995, p. 31.)

- (14) The value of statutory audit for the audited entity would be particularly enhanced if the communication between the statutory auditor or the audit firm, on the one hand, and the audit committee, on the other hand, were reinforced. Further to the regular dialogue during the carrying out of the statutory audit, it is important that the statutory auditor or the audit firm submit to the audit committee an additional and more detailed report on the results of the statutory audit. This additional report should be submitted to the audit committee no later than the audit report. Upon request, the statutory auditor or the audit firm should discuss key matters which have been mentioned in the additional report with the audit committee. In addition, it should be possible to make such additional detailed report available to competent authorities responsible for the oversight of statutory auditors and audit firms upon their request, and to third parties where national law so provides.
- (15) Statutory auditors or audit firms already provide competent authorities supervising public-interest entities with information on facts or decisions which could constitute a breach of the rules governing the activities of the audited entity or an impairment of the continuous functioning of the audited entity. However, supervisory tasks would be facilitated if supervisors of credit institutions and insurance undertakings and their statutory auditors and audit firms were required to establish an effective dialogue with each other.
- (16) Regulation (EU) No 1092/2010 of the European Parliament and of the Council ⁽¹⁾ established the European Systemic Risk Board (ESRB). The role of the ESRB is to monitor the build-up of systemic risk in the Union. Given the information that statutory auditors and audit firms of systemically important financial institutions have access to, their experience could help the ESRB in its work. Therefore an annual forum for dialogue between statutory auditors and audit firms, on the one hand, and ESRB, on the other, on a sectoral, anonymised basis should be facilitated by this Regulation.
- (17) In order to increase the confidence in, and the liability of, the statutory auditors and the audit firms carrying out the statutory audit of public-interest entities, it is important that the transparency reporting by statutory auditors and audit firms be increased. Therefore, statutory auditors and audit firms should be required to disclose financial information, showing in particular their total turnover divided into audit fees paid by public-interest entities, audit fees paid by other entities and fees for other services. They should also disclose financial information at the level of the network to which they belong. Statutory auditors and audit firms should provide additional supplementary information on audit fees to competent authorities with a view to facilitating their supervisory tasks.
- (18) It is important that the role of the audit committee in the selection of a new statutory auditor or audit firm be reinforced, in the interest of a more informed decision of the general meeting of shareholders or members of the audited entity. Hence, when making a proposal to the general meeting, the administrative or supervisory body should explain whether it follows the preference of the audit committee and, if not, why. The recommendation of the audit committee should include at least two possible choices for the audit engagement and a duly justified preference for one of them, so that a real choice can be made. In order to provide a fair and proper justification in its recommendation, the audit committee should use the results of a mandatory selection procedure organised by the audited entity, under the responsibility of the audit committee. In such selection procedure, the audited entity should not restrict statutory auditors or audit firms with a low market share from presenting proposals for the audit engagement. Tender documents should contain transparent and non-discriminatory selection criteria to be used for the evaluation of proposals. Considering, however, that this selection procedure could entail disproportionate costs for undertakings with reduced market capitalisation or small and medium-sized public-interest entities having regard to their size, it is appropriate to relieve such undertakings and entities from the obligation of organising a procedure for the selection of a new statutory auditor or audit firm.
- (19) The right of the general meeting of shareholders or members of the audited entity to choose the statutory auditor or the audit firm would be of no value if the audited entity were to enter into a contract with a third party providing for a restriction of such choice. Therefore, any clause of a contract entered into by the audited entity with a third party regarding the appointment or restricting the choice to particular statutory auditors or audit firms should be considered null and void.

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

- (20) The appointment of more than one statutory auditor or audit firm by public-interest entities would reinforce the professional scepticism and help to increase audit quality. Also, this measure, combined with the presence of smaller audit firms in the audit market would facilitate the development of the capacity of such firms, thus broadening the choice of statutory auditors and audit firms for public-interest entities. Therefore, the latter should be encouraged and incentivised to appoint more than one statutory auditor or audit firm to carry out the statutory audit.
- (21) In order to address the familiarity threat and therefore reinforce the independence of statutory auditors and audit firms, it is important to establish a maximum duration of the audit engagement of a statutory auditor or an audit firm in a particular audited entity. In addition, as a means of strengthening the independence of the statutory auditor or the audit firm, reinforcing professional scepticism, and increasing audit quality, this Regulation provides for the following alternatives for an extension of the maximum duration: regular and open mandatory retendering or the appointment of more than one statutory auditor or audit firm by public-interest entities. Also, the involvement of smaller audit firms in these measures would facilitate the development of the capacity of such firms, thus broadening the choice of statutory auditors and audit firms for public-interest entities. An appropriate gradual rotation mechanism should also be established with regard to the key audit partners carrying out the statutory audit on behalf of the audit firm. It is also important to provide for an appropriate period within which such statutory auditor or audit firm may not carry out the statutory audit of the same entity. In order to ensure a smooth transition, the former statutory auditor should transfer a handover file with relevant information to the incoming statutory auditor.
- (22) In order to ensure a high level of investor and consumer confidence in the internal market by avoiding conflicts of interests, statutory auditors and audit firms should be subject to appropriate oversight by competent authorities which are independent from the audit profession and which have adequate capacity, expertise and resources. Member States should be able to delegate or allow their competent authorities to delegate any of the tasks of those competent authorities to other authorities or bodies except those related to the quality assurance system, investigations and disciplinary systems. However, Member States should be able to choose to delegate tasks related to disciplinary systems to other authorities and bodies provided that the majority of the persons involved in the governance of the authority or body concerned are independent from the audit profession. The national competent authorities should have the necessary powers to undertake their supervisory tasks, including the capacity to access data, obtain information and carry out inspections. They should specialise in the supervision of financial markets, in the compliance with financial reporting obligations or in statutory audit oversight. However, it should be possible for the supervision of the compliance with the obligations imposed on public-interest entities to be carried out by the competent authorities responsible for the supervision of those entities. The funding of the competent authorities should be free from any undue influence by statutory auditors or audit firms.
- (23) The quality of supervision should improve if there is effective cooperation between authorities charged with different tasks at national level. Therefore, the authorities competent to supervise compliance with the obligations regarding statutory audit of public-interest entities should cooperate with the authorities responsible for the tasks provided for in Directive 2006/43/EC, with those supervising public-interest entities and with the financial intelligence units referred to in Directive 2005/60/EC of the European Parliament and of the Council ⁽¹⁾.
- (24) External quality assurance for the statutory audit is fundamental for high quality audit. It adds credibility to published financial information and provides better protection for shareholders, investors, creditors and other interested parties. Statutory auditors and audit firms should therefore be subject to a system of quality assurance under the responsibility of the competent authorities, thus ensuring objectivity and independence from the audit profession. Quality assurance reviews should be organised in such a manner that each statutory auditor or each audit firm carrying out audits of public-interest entities is subject to a quality assurance review on the basis of an analysis of the risks. In the case of statutory auditors and audit firms carrying out statutory audits of public-interest entities other than those defined in points (17) and (18) of Article 2 of Directive 2006/43/EC, that review

⁽¹⁾ Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (OJ L 309, 25.11.2005, p. 15.)

should take place at least every three years and, in other cases, at least every six years. The Commission Recommendation of 6 May 2008 on external quality assurance for statutory auditors and audit firms auditing public-interest entities ⁽¹⁾ provides information on how inspections should be undertaken. Quality assurance reviews should be appropriate and proportionate in view of the scale and complexity of the business of the reviewed statutory auditor or audit firm.

- (25) The market for the provision of statutory audit services to public-interest entities evolves over time. It is therefore necessary that competent authorities monitor the developments in the market, particularly as regards the risks that arise from high market concentration, including within specific sectors, and the performance of audit committees.
- (26) The transparency of the activities of competent authorities should help to increase the confidence of investors and consumers in the internal market. Therefore, competent authorities should be required to report regularly on their activities and to publish information in aggregated form on findings and conclusions of inspections, or in individual form where Member States so provide.
- (27) Cooperation between the competent authorities of the Member States can make an important contribution to ensuring consistently high quality of statutory audit in the Union. Therefore, the competent authorities of the Member States should cooperate with each other, where necessary, for the purpose of carrying out their supervisory duties regarding statutory audits. They should respect the principle of home-country regulation and oversight by the Member State in which the statutory auditor or the audit firm is approved and in which the audited entity has its registered office. The cooperation between competent authorities should be organised within the framework of a Committee of European Auditing Oversight Bodies (CEAOB), which should be composed of high-level representatives of the competent authorities. In order to enhance consistent application of this Regulation, the CEAOB should be able to adopt non-binding guidelines or opinions. In addition, it should facilitate the exchange of information, provide advice to the Commission and contribute to technical assessments and technical examinations.

For the purpose of carrying out the technical assessment of public oversight systems of third countries and to the international cooperation between Member States and third countries in this area, the CEAOB should establish a sub-group chaired by the member appointed by the European Supervisory Authority (European Securities and Markets Authority — ESMA) ⁽²⁾ and should request the assistance from ESMA, the European Supervisory Authority (European Banking Authority — EBA) ⁽³⁾ or the European Supervisory Authority (European Insurance and Occupational Pensions Authority — EIOPA) ⁽⁴⁾ insofar as its request is related to the international cooperation between Member States and third countries in the field of statutory audit of public-interest entities supervised by these European Supervisory Authorities. The Secretariat of the CEAOB should be provided by the Commission and, based on the work programme agreed by the CEAOB, should include related expenses in its estimates for the next year.

- (28) The scope of cooperation between the competent authorities of Member States should include cooperation with regard to quality assurance reviews and assistance with investigations related to the carrying-out of statutory audits of public-interest entities, including in cases where the conduct under investigation does not constitute an infringement of any legislative or regulatory provision in force in the Member States concerned. The detailed arrangements for cooperation between the competent authorities of the Member States should include the possibility of creating colleges of competent authorities and the delegation of tasks among themselves. The concept of a network in which statutory auditors and audit firms operate should be taken into account in such cooperation. Competent authorities should respect appropriate confidentiality and professional secrecy rules.

⁽¹⁾ OJ L 120, 7.5.2008, p. 20.

⁽²⁾ European Supervisory Authority established by Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

⁽³⁾ European Supervisory Authority established by Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

⁽⁴⁾ European Supervisory Authority established by Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

- (29) The interrelation of capital markets gives rise to the need to empower competent authorities to cooperate with supervisory authorities and bodies of third countries regarding the exchange of information or quality assurance reviews. However, where the cooperation with third country authorities is related to audit working papers or other documents held by statutory auditors or audit firms, the procedures laid down by Directive 2006/43/EC should apply.
- (30) Sustainable audit capacity and a competitive market for statutory audit services in which there is a sufficient choice of statutory auditors and audit firms capable of carrying out statutory audits of public-interest entities are required in order to ensure a smooth functioning of capital markets. The competent authorities and the European Competition Network (ECN) should report on the changes brought in the audit market structure introduced by this Regulation.
- (31) The alignment of the procedures for the adoption of delegated acts by the Commission to the Treaty on the Functioning of the European Union and, in particular, to Article 290 and 291 thereof, should be effected on a case-by-case basis. In order to take into account the developments in auditing and in the audit profession, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. In particular, delegated acts are necessary for the purpose of adopting international auditing standards in the area of audit practice, independence of and internal controls of statutory auditors and audit firms. The international auditing standards adopted should not amend any requirements of this Regulation or supplement any of those requirements, except for those precisely defined. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including consultations at expert level.

The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

- (32) In order to ensure legal certainty and the smooth transition to the regime introduced by this Regulation, it is important to introduce a transitional period regarding the entry into force of the obligation to rotate statutory auditors and audit firms and the obligation to organise a selection procedure for the choice of statutory auditors and audit firms.
- (33) References to provisions of Directive 2006/43/EC should be understood as references to the national provisions transposing those provisions of Directive 2006/43/EC. The new European audit framework as established by this Regulation and Directive 2014/56/EU of the European Parliament and of the Council ⁽¹⁾ replaces existing requirements laid down in Directive 2006/43/EC and should be interpreted without referring to any preceding instruments such as Commission recommendations adopted under the previous framework.
- (34) Since the objectives of this Regulation, namely clarifying and better defining the role of statutory audit regarding public-interest entities, improving the information that the statutory auditor or the audit firm provides to the audited entity, investors and other stakeholders, improving the communication channels between auditors and supervisors of public-interest entities, preventing any conflict of interest arising from the provision of non-audit services to public-interest entities, mitigating the risk of any potential conflict of interest due to the existing system whereby the auditee selects and pays the auditor or the familiarity threat, facilitating the switching of, and the choice of a statutory auditor or an audit firm to public-interest entities, broadening the choice of statutory auditors and audit firms for public-interest entities and improving the effectiveness, independence and consistency of the regulation and oversight of statutory auditors and audit firms providing statutory audits to public-interest entities including as regards cooperation at Union level, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

⁽¹⁾ Directive 2014/56/EU of the European Parliament and the Council of 16 April 2014 amending Directive 2006/43/EC on statutory audits of annual accounts and consolidated accounts (see page 196 of this Official Journal).

- (35) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, notably the right to respect for private and family life, the right to the protection of personal data, and the freedom to conduct a business, and has to be applied in accordance with those rights and principles.
- (36) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 of the European Parliament and of the Council and delivered an opinion on 23 April 2012 ⁽¹⁾.
- (37) A new legal framework of statutory audit of annual and consolidated financial statements should be established by this Regulation and Directive 2014/56/EU, therefore Commission Decision 2005/909/EC ⁽²⁾ should be repealed,

HAVE ADOPTED THIS REGULATION:

TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down requirements for the carrying out of the statutory audit of annual and consolidated financial statements of public-interest entities, rules on the organisation and selection of statutory auditors and audit firms by public-interest entities to promote their independence and the avoidance of conflicts of interest and rules on the supervision of compliance by statutory auditors and audit firms with those requirements.

Article 2

Scope

1. This Regulation shall apply to the following:
 - (a) statutory auditors and audit firms carrying out statutory audits of public-interest entities;
 - (b) public-interest entities.
2. This Regulation shall apply without prejudice to Directive 2006/43/EC.
3. Where a cooperative within the meaning of point (14) of Article 2 of Directive 2006/43/EC, a savings bank or a similar entity as referred to in Article 45 of Directive 86/635/EEC, or a subsidiary or a legal successor of a cooperative, a savings bank or a similar entity as referred to in Article 45 of Directive 86/635/EEC is required or permitted under national provisions to be a member of a non-profit-making auditing entity, the Member State may decide that this Regulation or certain provisions of it shall not apply to the statutory audit of such entity, provided that the principles of independence laid down in Directive 2006/43/EC are complied with by the statutory auditor when carrying out the statutory audit of one of its members and by persons who may be in a position to influence the statutory audit.

⁽¹⁾ OJ C 336, 6.11.2012, p. 4.

⁽²⁾ Commission Decision 2005/909/EC of 14 December 2005 setting up a group of experts to advise the Commission and to facilitate co-operation between public oversight systems for statutory auditors and audit firms (OJ L 329, 16.12.2005, p. 38.)

4. Where a cooperative within the meaning of point (14) of Article 2 of Directive 2006/43/EC, a savings bank or a similar entity as referred to in Article 45 of Directive 86/635/EEC, or a subsidiary or a legal successor of a cooperative, a savings bank or a similar entity as referred to in Article 45 of Directive 86/635/EEC is required or permitted under national provisions to be a member of a non-profit-making auditing entity, an objective, reasonable and informed party would not conclude that the membership-based relationship compromises the statutory auditor's independence, provided that when such an auditing entity is conducting a statutory audit of one of its members, the principles of independence are applied to the statutory auditors carrying out the audit and those persons who may be in a position to influence the statutory audit.

5. The Member State shall inform the Commission and the Committee of European Auditing Oversight Bodies (hereinafter referred to as 'the CEAOB'), referred to in Article 30, of such exceptional situations of non-application of this Regulation or certain provisions of this Regulation. It shall communicate to the Commission and the CEAOB the list of provisions of this Regulation that do not apply to the statutory audit of the entities referred to in paragraph 3 of this Article and the reasons that justified such non-application.

Article 3

Definitions

For the purposes of this Regulation, the definitions laid down in Article 2 of Directive 2006/43/EC shall apply, except as regards the term 'competent authority' as provided for in Article 20 of this Regulation.

TITLE II

CONDITIONS FOR CARRYING OUT STATUTORY AUDIT OF PUBLIC INTEREST ENTITIES

Article 4

Audit fees

1. Fees for the provision of statutory audits to public-interest entities shall not be contingent fees.

Without prejudice to Article 25 of Directive 2006/43/EC, for the purposes of the first subparagraph, contingent fees means fees for audit engagements calculated on a predetermined basis relating to the outcome or result of a transaction or the result of the work performed. Fees shall not be regarded as being contingent if a court or a competent authority has established them.

2. When the statutory auditor or the audit firm provides to the audited entity, its parent undertaking or its controlled undertakings, for a period of three or more consecutive financial years, non-audit services other than those referred to in Article 5(1) of this Regulation, the total fees for such services shall be limited to no more than 70 % of the average of the fees paid in the last three consecutive financial years for the statutory audit(s) of the audited entity and, where applicable, of its parent undertaking, of its controlled undertakings and of the consolidated financial statements of that group of undertakings.

For the purposes of the limits specified in the first subparagraph, non-audit services, other than those referred to in Article 5(1), required by Union or national legislation shall be excluded.

Member States may provide that a competent authority may, upon a request by the statutory auditor or the audit firm, on an exceptional basis, allow that statutory auditor or audit firm to be exempt from the requirements in the first subparagraph in respect of an audited entity for a period not exceeding two financial years.

3. When the total fees received from a public-interest entity in each of the last three consecutive financial years are more than 15 % of the total fees received by the statutory auditor or the audit firm or, where applicable, by the group auditor carrying out the statutory audit, in each of those financial years, such a statutory auditor or audit firm or, as the case may be, group auditor, shall disclose that fact to the audit committee and discuss with the audit committee the threats to their independence and the safeguards applied to mitigate those threats. The audit committee shall consider whether the audit engagement should be subject to an engagement quality control review by another statutory auditor or audit firm prior to the issuance of the audit report.

Where the fees received from such a public-interest entity continue to exceed 15 % of the total fees received by such a statutory auditor or audit firm or, as the case may be, by a group auditor carrying out the statutory audit, the audit committee shall decide on the basis of objective grounds whether the statutory auditor or the audit firm or the group auditor, of such an entity or group of entities may continue to carry out the statutory audit for an additional period which shall not, in any case, exceed two years.

4. Member States may apply more stringent requirements than set out in this Article.

Article 5

Prohibition of the provision of non-audit services

1. A statutory auditor or an audit firm carrying out the statutory audit of a public-interest entity, or any member of the network to which the statutory auditor or the audit firm belongs, shall not directly or indirectly provide to the audited entity, to its parent undertaking or to its controlled undertakings within the Union any prohibited non-audit services in:

- (a) the period between the beginning of the period audited and the issuing of the audit report; and
- (b) the financial year immediately preceding the period referred to in point (a) in relation to the services listed in point (g) of the second subparagraph.

For the purposes of this Article, prohibited non-audit services shall mean:

- (a) tax services relating to:
 - (i) preparation of tax forms;
 - (ii) payroll tax;
 - (iii) customs duties;
 - (iv) identification of public subsidies and tax incentives unless support from the statutory auditor or the audit firm in respect of such services is required by law;
 - (v) support regarding tax inspections by tax authorities unless support from the statutory auditor or the audit firm in respect of such inspections is required by law;
 - (vi) calculation of direct and indirect tax and deferred tax;
 - (vii) provision of tax advice;
- (b) services that involve playing any part in the management or decision-making of the audited entity;
- (c) bookkeeping and preparing accounting records and financial statements;
- (d) payroll services;
- (e) designing and implementing internal control or risk management procedures related to the preparation and/or control of financial information or designing and implementing financial information technology systems;

- (f) valuation services, including valuations performed in connection with actuarial services or litigation support services;
- (g) legal services, with respect to:
 - (i) the provision of general counsel;
 - (ii) negotiating on behalf of the audited entity; and
 - (iii) acting in an advocacy role in the resolution of litigation;
- (h) services related to the audited entity's internal audit function;
- (i) services linked to the financing, capital structure and allocation, and investment strategy of the audited entity, except providing assurance services in relation to the financial statements, such as the issuing of comfort letters in connection with prospectuses issued by the audited entity;
- (j) promoting, dealing in, or underwriting shares in the audited entity;
- (k) human resources services, with respect to:
 - (i) management in a position to exert significant influence over the preparation of the accounting records or financial statements which are the subject of the statutory audit, where such services involve:
 - searching for or seeking out candidates for such position; or
 - undertaking reference checks of candidates for such positions;
 - (ii) structuring the organisation design; and
 - (iii) cost control.

2. Member States may prohibit services other than those listed in paragraph 1 where they consider that those services represent a threat to independence. Member States shall communicate to the Commission any additions to the list in paragraph 1.

3. By way of derogation from the second subparagraph of paragraph 1, Member States may allow the provision of the services referred to in points (a) (i), (a) (iv) to (a) (vii) and (f), provided that the following requirements are complied with:

- (a) they have no direct or have immaterial effect, separately or in the aggregate on the audited financial statements;
- (b) the estimation of the effect on the audited financial statements is comprehensively documented and explained in the additional report to the audit committee referred to in Article 11; and
- (c) the principles of independence laid down in Directive 2006/43/EC are complied with by the statutory auditor or the audit firm.

4. A statutory auditor or an audit firm carrying out statutory audits of public-interest entities and, where the statutory auditor or the audit firm belongs to a network, any member of such network, may provide to the audited entity, to its parent undertaking or to its controlled undertakings non-audit services other than the prohibited non-audit services referred to in paragraphs 1 and 2 subject to the approval of the audit committee after it has properly assessed threats to independence and the safeguards applied in accordance with Article 22b of Directive 2006/43/EC. The audit committee shall, where applicable, issue guidelines with regard to the services referred to in paragraph 3.

Member States may establish stricter rules setting out the conditions under which a statutory auditor, an audit firm or a member of a network to which the statutory auditor or audit firm belongs may provide to the audited entity, to its parent undertaking or to its controlled undertakings non-audit services other than the prohibited non-audit services referred to in paragraph 1.

5. When a member of a network to which the statutory auditor or the audit firm carrying out a statutory audit of a public-interest entity belongs provides any of the non-audit services, referred to in paragraphs 1 and 2 of this Article, to an undertaking incorporated in a third country which is controlled by the audited public-interest entity, the statutory auditor or the audit firm concerned shall assess whether his, her or its independence would be compromised by such provision of services by the member of the network.

If his, her or its independence is affected, the statutory auditor or the audit firm shall apply safeguards where applicable in order to mitigate the threats caused by such provision of services in a third country. The statutory auditor or the audit firm may continue to carry out the statutory audit of the public-interest entity only if he, she or it can justify, in accordance with Article 6 of this Regulation and Article 22b of Directive 2006/43/EC, that such provision of services does not affect his, her or its professional judgement and the audit report.

For the purposes of this paragraph:

- (a) being involved in the decision-taking of the audited entity and the provision of the services referred to in points (b), (c) and (e) of the second subparagraph of paragraph 1 shall be deemed to affect such independence in all cases and to be incapable of mitigation by any safeguards.
- (b) provision of the services referred to in the second subparagraph of paragraph 1 other than points (b), (c) and (e) thereof shall be deemed to affect such independence and therefore to require safeguards to mitigate the threats caused thereby.

Article 6

Preparation for the statutory audit and assessment of threats to independence

1. Before accepting or continuing an engagement for a statutory audit of a public-interest entity, a statutory auditor or an audit firm shall assess and document, in addition to the provisions of Article 22b of Directive 2006/43/EC, the following:

- (a) whether he, she or it complies with the requirements of Articles 4 and 5 of this Regulation;
- (b) whether the conditions of Article 17 of this Regulation are complied with;
- (c) without prejudice to Directive 2005/60/EC, the integrity of the members of the supervisory, administrative and management bodies of the public-interest entity.

2. A statutory auditor or an audit firm shall:

- (a) confirm annually in writing to the audit committee that the statutory auditor, the audit firm and partners, senior managers and managers, conducting the statutory audit are independent from the audited entity;
- (b) discuss with the audit committee the threats to their independence and the safeguards applied to mitigate those threats, as documented by them pursuant to paragraph 1.

Article 7

Irregularities

Without prejudice to Article 12 of this Regulation and Directive 2005/60/EC, when a statutory auditor or an audit firm carrying out the statutory audit of a public-interest entity suspects or has reasonable grounds to suspect that irregularities, including fraud with regard to the financial statements of the audited entity, may occur or have occurred, he, she or it shall inform the audited entity and invite it to investigate the matter and take appropriate measures to deal with such irregularities and to prevent any recurrence of such irregularities in the future.

Where the audited entity does not investigate the matter, the statutory auditor or the audit firm shall inform the authorities as designated by the Member States responsible for investigating such irregularities.

The disclosure in good faith to those authorities, by the statutory auditor or the audit firm, of any irregularities referred to in the first subparagraph shall not constitute a breach of any contractual or legal restriction on disclosure of information.

Article 8

Engagement quality control review

1. Before the reports referred to in Articles 10 and 11 are issued, an engagement quality control review (in this Article hereinafter referred to as: review) shall be performed to assess whether the statutory auditor or the key audit partner could reasonably have come to the opinion and conclusions expressed in the draft of these reports.
2. The review shall be performed by an engagement quality control reviewer (in this Article hereinafter referred to as: reviewer). The reviewer shall be a statutory auditor who is not involved in the performance of the statutory audit to which the review relates.
3. By way of derogation from paragraph 2, where the statutory audit is carried out by an audit firm and all the statutory auditors were involved in the carrying-out of the statutory audit, or where the statutory audit is carried out by a statutory auditor and the statutory auditor is not a partner or employee of an audit firm, he, she or it shall arrange for another statutory auditor to perform a review. The disclosure of documents or information to the independent reviewer for the purposes of this Article shall not constitute a breach of professional secrecy. Documents or information disclosed to the reviewer for the purposes of this Article shall be subject to professional secrecy.
4. When performing the review, the reviewer shall record at least the following:
 - (a) the oral and written information provided by the statutory auditor or the key audit partner to support the significant judgements as well as the main findings of the audit procedures carried out and the conclusions drawn from those findings, whether or not at the request of the reviewer;
 - (b) the opinions of the statutory auditor or the key audit partner, as expressed in the draft of the reports referred to in Articles 10 and 11;
5. The review shall at least assess the following elements:
 - (a) the independence of the statutory auditor or the audit firm from the audited entity;
 - (b) the significant risks which are relevant to the statutory audit and which the statutory auditor or the key audit partner has identified during the performance of the statutory audit and the measures that he or she has taken to adequately manage those risks;
 - (c) the reasoning of the statutory auditor or the key audit partner, in particular with regard to the level of materiality and the significant risks referred to in point (b);
 - (d) any request for advice to external experts and the implementation of such advice;
 - (e) the nature and scope of the corrected and uncorrected misstatements in the financial statements that were identified during the carrying out of the audit;
 - (f) the subjects discussed with the audit committee and the management and/or supervisory bodies of the audited entity;
 - (g) the subjects discussed with competent authorities and, where applicable, with other third parties;
 - (h) whether the documents and information selected from the file by the reviewer support the opinion of the statutory auditor or the key audit partner as expressed in the draft of the reports referred to in Articles 10 and 11.

6. The reviewer shall discuss the results of the review with the statutory auditor or the key audit partner. The audit firm shall establish procedures for determining the manner in which any disagreement between the key audit partner and the reviewer are to be resolved.

7. The statutory auditor or the audit firm and the reviewer shall keep a record of the results of the review, together with the considerations underlying those results.

Article 9

International auditing standards

The Commission shall be empowered to adopt by means of delegated acts in accordance with Article 39 the international auditing standards referred to in Article 26 of Directive 2006/43/EC in the area of audit practice, and the independence and internal quality controls of statutory auditors and audit firms for the purposes of their application within the Union, provided they meet the requirements of points (a), (b) and (c) of Article 26(3) of Directive 2006/43/EC and do not amend any of the requirements of this Regulation or supplement any of its requirements apart from those set out in Articles 7, 8 and 18 of this Regulation.

Article 10

Audit report

1. The statutory auditor(s) or the audit firm(s) shall present the results of the statutory audit of the public-interest entity in an audit report.

2. The audit report shall be prepared in accordance with the provisions of Article 28 of Directive 2006/43/EC and in addition shall at least:

- (a) state by whom or by which body the statutory auditor(s) or the audit firm(s) was (were) appointed;
- (b) indicate the date of the appointment and the period of total uninterrupted engagement including previous renewals and reappointments of the statutory auditors or the audit firms;
- (c) provide, in support of the audit opinion, the following:
 - (i) a description of the most significant assessed risks of material misstatement, including assessed risks of material misstatement due to fraud;
 - (ii) a summary of the auditor's response to those risks; and
 - (iii) where relevant, key observations arising with respect to those risks.

Where relevant to the above information provided in the audit report concerning each significant assessed risk of material misstatement, the audit report shall include a clear reference to the relevant disclosures in the financial statements.

- (d) explain to what extent the statutory audit was considered capable of detecting irregularities, including fraud;
- (e) confirm that the audit opinion is consistent with the additional report to the audit committee referred to in Article 11;
- (f) declare that the prohibited non-audit services referred to in Article 5(1) were not provided and that the statutory auditor(s) or the audit firm(s) remained independent of the audited entity in conducting the audit;
- (g) indicate any services, in addition to the statutory audit, which were provided by the statutory auditor or the audit firm to the audited entity and its controlled undertaking(s), and which have not been disclosed in the management report or financial statements.

Member States may lay down additional requirements in relation to the content of the audit report.

3. Except as required by point (e) of paragraph 2 the audit report shall not contain any cross-references to the additional report to the audit committee referred to in Article 11. The audit report shall be in clear and unambiguous language.
4. The statutory auditor or the audit firm shall not use the name of any competent authority in a way that would indicate or suggest endorsement or approval by that authority of the audit report.

Article 11

Additional report to the audit committee

1. Statutory auditors or audit firms carrying out statutory audits of public-interest entities shall submit an additional report to the audit committee of the audited entity not later than the date of submission of the audit report referred to in Article 10. Member States may additionally require that this additional report be submitted to the administrative or supervisory body of the audited entity.

If the audited entity does not have an audit committee, the additional report shall be submitted to the body performing equivalent functions within the audited entity. Member States may allow the audit committee to disclose that additional report to such third parties as are provided for in their national law.

2. The additional report to the audit committee shall be in writing. It shall explain the results of the statutory audit carried out and shall at least:
 - (a) include the declaration of independence referred to in point (a) of Article 6(2);
 - (b) where the statutory audit was carried out by an audit firm, the report shall identify each key audit partner involved in the audit;
 - (c) where the statutory auditor or the audit firm has made arrangements for any of his, her or its activities to be conducted by another statutory auditor or audit firm that is not a member of the same network, or has used the work of external experts, the report shall indicate that fact and shall confirm that the statutory auditor or the audit firm received a confirmation from the other statutory auditor or audit firm and/or the external expert regarding their independence;
 - (d) describe the nature, frequency and extent of communication with the audit committee or the body performing equivalent functions within the audited entity, the management body and the administrative or supervisory body of the audited entity, including the dates of meetings with those bodies;
 - (e) include a description of the scope and timing of the audit;
 - (f) where more than one statutory auditor or audit firm have been appointed, describe the distribution of tasks among the statutory auditors and/or the audit firms;
 - (g) describe the methodology used, including which categories of the balance sheet have been directly verified and which categories have been verified based on system and compliance testing, including an explanation of any substantial variation in the weighting of system and compliance testing when compared to the previous year, even if the previous year's statutory audit was carried out by other statutory auditor(s) or audit firm(s);
 - (h) disclose the quantitative level of materiality applied to perform the statutory audit for the financial statements as a whole and where applicable the materiality level or levels for particular classes of transactions, account balances or disclosures, and disclose the qualitative factors which were considered when setting the level of materiality;
 - (i) report and explain judgements about events or conditions identified in the course of the audit that may cast significant doubt on the entity's ability to continue as a going concern and whether they constitute a material uncertainty, and provide a summary of all guarantees, comfort letters, undertakings of public intervention and other support measures that have been taken into account when making a going concern assessment;

- (j) report on any significant deficiencies in the audited entity's or, in the case of consolidated financial statements, the parent undertaking's internal financial control system, and/or in the accounting system. For each such significant deficiency, the additional report shall state whether or not the deficiency in question has been resolved by the management;
- (k) report any significant matters involving actual or suspected non-compliance with laws and regulations or articles of association which were identified in the course of the audit, in so far as they are considered to be relevant in order to enable the audit committee to fulfil its tasks;
- (l) report and assess the valuation methods applied to the various items in the annual or consolidated financial statements including any impact of changes of such methods;
- (m) in the case of a statutory audit of consolidated financial statements, explain the scope of consolidation and the exclusion criteria applied by the audited entity to the non-consolidated entities, if any, and whether those criteria applied are in accordance with the financial reporting framework;
- (n) where applicable, identify any audit work performed by third-country auditor(s), statutory auditor(s), third-country audit entity(ies) or audit firm(s) in relation to a statutory audit of consolidated financial statements other than by members of the same network as to which the auditor of the consolidated financial statements belongs;
- (o) indicate whether all requested explanations and documents were provided by the audited entity;
- (p) report:
 - (i) any significant difficulties encountered in the course of the statutory audit;
 - (ii) any significant matters arising from the statutory audit that were discussed or were the subject of correspondence with management; and
 - (iii) any other matters arising from the statutory audit that in the auditor's professional judgement, are significant to the oversight of the financial reporting process.

Member States may lay down additional requirements in relation to the content of the additional report to the audit committee.

Upon request by a statutory auditor, an audit firm or the audit committee, the statutory auditor(s) or the audit firm(s) shall discuss key matters arising from the statutory audit, referred to in the additional report to the audit committee, and in particular in point (j) of the first subparagraph, with the audit committee, administrative body or, where applicable, supervisory body of the audited entity.

3. Where more than one statutory auditor or audit firm have been engaged simultaneously, and any disagreement has arisen between them on auditing procedures, accounting rules or any other issue regarding the conduct of the statutory audit, the reasons for such disagreement shall be explained in the additional report to the audit committee.

4. The additional report to the audit committee shall be signed and dated. Where an audit firm carries out the statutory audit, the additional report to the audit committee shall be signed by the statutory auditors carrying out the statutory audit on behalf of the audit firm.

5. Upon request, and in accordance with national law, the statutory auditors or the audit firms shall make available without delay the additional report to the competent authorities within the meaning of Article 20(1).

Article 12

Report to supervisors of public-interest entities

1. Without prejudice to Article 55 of Directive 2004/39/EC, Article 63 of Directive 2013/36/EU of the European Parliament and of the Council ⁽¹⁾, Article 15(4) of Directive 2007/64/EC, Article 106 of Directive 2009/65/EC, Article 3(1) of Directive 2009/110/EC and Article 72 of Directive 2009/138/EC of the European Parliament and of the Council ⁽²⁾, the statutory auditor or the audit firm carrying out the statutory audit of a public-interest entity shall have a duty to report promptly to the competent authorities supervising that public-interest entity or, where so determined by the Member State concerned, to the competent authority responsible for the oversight of the statutory auditor or audit firm, any information concerning that public-interest entity of which he, she or it has become aware while carrying out that statutory audit and which may bring about any of the following:

- (a) a material breach of the laws, regulations or administrative provisions which lay down, where appropriate, the conditions governing authorisation or which specifically govern pursuit of the activities of such public-interest entity;
- (b) a material threat or doubt concerning the continuous functioning of the public-interest entity;
- (c) a refusal to issue an audit opinion on the financial statements or the issuing of an adverse or qualified opinion.

Statutory auditors or audit firms shall also have a duty to report any information referred to in points (a) (b) or (c) of the first subparagraph of which they become aware in the course of carrying out the statutory audit of an undertaking having close links with the public-interest entity for which they are also carrying out the statutory audit. For the purposes of this Article, 'close links' shall have the meaning assigned to that term in point (38) of Article 4(1) of Regulation (EU) No 575/2013 of the European Parliament and of the Council ⁽³⁾.

Member States may require additional information from the statutory auditor or the audit firm provided it is necessary for effective financial market supervision as provided for in national law.

2. An effective dialogue shall be established between the competent authorities supervising credit institutions and insurance undertakings, on the one hand, and the statutory auditor(s) and the audit firm(s) carrying out the statutory audit of those institutions and undertakings, on the other hand. The responsibility for compliance with this requirement shall rest with both parties to the dialogue.

At least once a year, the European Systemic Risk Board (ESRB) and the CEAOB shall organise a meeting with the statutory auditors and the audit firms or networks carrying out statutory audits of all global systemically important financial institutions authorised within the Union, as identified internationally, in order to inform the ESRB of sectoral or any significant developments in those systemically important financial institutions.

In order to facilitate the exercise of the tasks referred to in the first subparagraph, the European Supervisory Authority (European Banking Authority — EBA) and the European Supervisory Authority (European Insurance and Occupational Pensions Authority — EIOPA) shall, taking current supervisory practices into account, issue guidelines addressed to the competent authorities supervising credit institutions and insurance undertakings, in accordance with Article 16 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ⁽⁴⁾ and Article 16 of Regulation (EU) No 1094/2010 of the European Parliament and of the Council ⁽⁵⁾, respectively.

⁽¹⁾ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338.)

⁽²⁾ Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1.)

⁽³⁾ Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

⁽⁴⁾ Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

⁽⁵⁾ Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

3. The disclosure in good faith to the competent authorities or to ESRB and the CEAOB, by the statutory auditor or the audit firm or network, where applicable, of any information referred to in paragraph 1 or of any information emerging during the dialogue provided for in paragraph 2 shall not constitute a breach of any contractual or legal restriction on disclosure of information.

Article 13

Transparency report

1. A statutory auditor or an audit firm that carries out statutory audits of public-interest entities shall make public an annual transparency report at the latest four months after the end of each financial year. That transparency report shall be published on the website of the statutory auditor or the audit firm and shall remain available on that website for at least five years from the day of its publication on the website. If the statutory auditor is employed by an audit firm, the obligations under this Article shall be incumbent on the audit firm.

A statutory auditor or an audit firm shall be allowed to update its published annual transparency report. In such a case, the statutory auditor or the audit firm shall indicate that it is an updated version of the report and the original version of the report shall continue to remain available on the website.

Statutory auditors and audit firms shall communicate to the competent authorities that the transparency report has been published on the website of the statutory auditor or the audit firm or, as appropriate, that it has been updated.

2. The annual transparency report shall include at least the following:

- (a) a description of the legal structure and ownership of the audit firm;
- (b) where the statutory auditor or the audit firm is a member of a network:
 - (i) a description of the network and the legal and structural arrangements in the network;
 - (ii) the name of each statutory auditor operating as a sole practitioner or audit firm that is a member of the network;
 - (iii) the countries in which each statutory auditor operating as a sole practitioner or audit firm that is a member of the network is qualified as a statutory auditor or has his, her or its registered office, central administration or principal place of business;
 - (iv) the total turnover achieved by the statutory auditors operating as sole practitioners and audit firms that are members of the network, resulting from the statutory audit of annual and consolidated financial statements;
- (c) a description of the governance structure of the audit firm;
- (d) a description of the internal quality control system of the statutory auditor or of the audit firm and a statement by the administrative or management body on the effectiveness of its functioning;
- (e) an indication of when the last quality assurance review referred to in Article 26 was carried out;
- (f) a list of public-interest entities for which the statutory auditor or the audit firm carried out statutory audits during the preceding financial year;
- (g) a statement concerning the statutory auditor's or the audit firm's independence practices which also confirms that an internal review of independence compliance has been conducted;
- (h) a statement on the policy followed by the statutory auditor or the audit firm concerning the continuing education of statutory auditors referred to in Article 13 of Directive 2006/43/EC;

- (i) information concerning the basis for the partners' remuneration in audit firms;
- (j) a description of the statutory auditor's or the audit firm's policy concerning the rotation of key audit partners and staff in accordance with Article 17(7);
- (k) where not disclosed in its financial statements within the meaning of Article 4(2) of Directive 2013/34/EU, information about the total turnover of the statutory auditor or the audit firm, divided into the following categories:
 - (i) revenues from the statutory audit of annual and consolidated financial statements of public-interest entities and entities belonging to a group of undertakings whose parent undertaking is a public-interest entity;
 - (ii) revenues from the statutory audit of annual and consolidated financial statements of other entities;
 - (iii) revenues from permitted non-audit services to entities that are audited by the statutory auditor or the audit firm; and
 - (iv) revenues from non-audit services to other entities.

The statutory auditor or the audit firm may, in exceptional circumstances, decide not to disclose the information required in point (f) of the first subparagraph to the extent necessary to mitigate an imminent and significant threat to the personal security of any person. The statutory auditor or the audit firm shall be able to demonstrate to the competent authority the existence of such threat.

3. The transparency report shall be signed by the statutory auditor or the audit firm.

Article 14

Information for competent authorities

Statutory auditors and audit firms shall provide annually to his, her or its competent authority a list of the audited public-interest entities by revenue generated from them, dividing those revenues into:

- (a) revenues from statutory audit;
- (b) revenues from non-audit services other than those referred to in Article 5(1) which are required by Union or national legislation; and,
- (c) revenues from non-audit services other than those referred to in Article 5(1) which are not required by Union or national legislation.

Article 15

Record keeping

Statutory auditors and audit firms shall keep the documents and information referred to in Article 4(3), Article 6, Article 7, Article 8(4) to (7), Articles 10 and 11 Article 12(1) and (2), Article 14, Article 16(2), (3) and(5) of this Regulation, and in Articles 22b, 24a, 24b, 27 and 28 of Directive 2006/43/EC, for a period of at least five years following the creation of such documents or information.

Member States may require statutory auditors and audit firms to keep the documents and information referred to in the first subparagraph for a longer period in accordance with their rules on personal data protection and administrative and judicial proceedings.

TITLE III

THE APPOINTMENT OF STATUTORY AUDITORS OR AUDIT FIRMS BY PUBLIC-INTEREST ENTITIES

Article 16

Appointment of statutory auditors or audit firms

1. For the purposes of the application of Article 37(1) of Directive 2006/43/EC, for the appointment of statutory auditors or audit firms by public-interest entities, the conditions set out in paragraphs 2 to 5 of this Article shall apply, but may be subject to paragraph 7.

Where Article 37(2) of Directive 2006/43/EC applies, the public-interest entity shall inform the competent authority of the use of the alternative systems or modalities referred to in that Article. In that event, paragraphs 2 to 5 of this Article shall not apply.

2. The audit committee shall submit a recommendation to the administrative or supervisory body of the audited entity for the appointment of statutory auditors or audit firms.

Unless it concerns the renewal of an audit engagement in accordance with Article 17(1) and 17(2), the recommendation shall be justified and contain at least two choices for the audit engagement and the audit committee shall express a duly justified preference for one of them.

In its recommendation, the audit committee shall state that its recommendation is free from influence by a third party and that no clause of the kind referred to in paragraph 6 has been imposed upon it.

3. Unless it concerns the renewal of an audit engagement in accordance with Article 17(1) and 17(2), the recommendation of the audit committee referred to in paragraph 2 of this Article shall be prepared following a selection procedure organised by the audited entity respecting the following criteria:

- (a) the audited entity shall be free to invite any statutory auditors or audit firms to submit proposals for the provision of the statutory audit service on the condition that Article 17(3) is respected and that the organisation of the tender process does not in any way preclude the participation in the selection procedure of firms which received less than 15 % of the total audit fees from public-interest entities in the Member State concerned in the previous calendar year;
- (b) the audited entity shall prepare tender documents for the attention of the invited statutory auditors or audit firms. Those tender documents shall allow them to understand the business of the audited entity and the type of statutory audit that is to be carried out. The tender documents shall contain transparent and non-discriminatory selection criteria that shall be used by the audited entity to evaluate the proposals made by statutory auditors or audit firms;
- (c) the audited entity shall be free to determine the selection procedure and may conduct direct negotiations with interested tenderers in the course of the procedure;
- (d) where, in accordance with Union or national law, the competent authorities referred to in Article 20 require statutory auditors and audit firms to comply with certain quality standards, those standards shall be included in the tender documents;
- (e) the audited entity shall evaluate the proposals made by the statutory auditors or the audit firms in accordance with the selection criteria predefined in the tender documents. The audited entity shall prepare a report on the conclusions of the selection procedure, which shall be validated by the audit committee. The audited entity and the audit committee shall take into consideration any findings or conclusions of any inspection report on the applicant statutory auditor or audit firm referred to in Article 26(8) and published by the competent authority pursuant to point (d) of Article 28;

- (f) the audited entity shall be able to demonstrate, upon request, to the competent authority referred to in Article 20 that the selection procedure was conducted in a fair manner.

The audit committee shall be responsible for the selection procedure referred to in the first subparagraph.

For the purposes of point (a) of the first subparagraph, the competent authority referred to in Article 20(1) shall make public a list of the statutory auditors and the audit firms concerned which shall be updated on an annual basis. The competent authority shall use the information provided by statutory auditors and audit firms pursuant to Article 14 to make the relevant calculations.

4. Public-interest entities which meet the criteria set out in points (f) and (t) of Article 2(1) of Directive 2003/71/EC shall not be required to apply the selection procedure referred to in paragraph 3.

5. The proposal to the general meeting of shareholders or members of the audited entity for the appointment of statutory auditors or audit firms shall include the recommendation and preference referred to in paragraph 2 made by the audit committee or the body performing equivalent functions.

If the proposal departs from the preference of the audit committee, the proposal shall justify the reasons for not following the recommendation of the audit committee. However, the statutory auditor or audit firm recommended by the administrative or supervisory body must have participated in the selection procedure described in paragraph 3. This subparagraph shall not apply where the audit committee's functions are performed by the administrative or supervisory body.

6. Any clause of a contract entered into between a public-interest entity and a third party restricting the choice by the general meeting of shareholders or members of that entity, as referred to in Article 37 of Directive 2006/43/EC to certain categories or lists of statutory auditors or audit firms, as regards the appointment of a particular statutory auditor or audit firm to carry out the statutory audit of that entity shall be null and void.

The public-interest entity shall inform the competent authorities referred to in Article 20 directly and without delay of any attempt by a third party to impose such a contractual clause or to otherwise improperly influence the decision of the general meeting of shareholders or members on the selection of a statutory auditor or an audit firm.

7. Member States may decide that a minimum number of statutory auditors or audit firms are to be appointed by public-interest entities in certain circumstances and establish the conditions governing the relations between the statutory auditors or audit firms appointed.

If a Member State establishes any such requirement, it shall inform the Commission and the relevant European Supervisory Authority thereof.

8. Where the audited entity has a nomination committee in which shareholders or members have a considerable influence and which has the task of making recommendations on the selecting of auditors, Member States may allow that nomination committee to perform the functions of the audit committee that are laid down in this Article and require it to submit the recommendation referred to in paragraph 2 to the general meeting of shareholders or members.

Article 17

Duration of the audit engagement

1. A public-interest entity shall appoint a statutory auditor or an audit firm for an initial engagement of at least one year. The engagement may be renewed.

Neither the initial engagement of a particular statutory auditor or audit firm, nor this in combination with any renewed engagements therewith shall exceed a maximum duration of 10 years.

2. By way of derogation from paragraph 1, Member States may
 - (a) require that the initial engagement referred to in paragraph 1 be for a period of more than one year;
 - (b) set a maximum duration of less than 10 years for the engagements referred to in the second subparagraph of paragraph 1.
3. After the expiry of the maximum durations of engagements referred to in the second subparagraph of paragraph 1, or in point (b) of paragraph 2, or after the expiry of the durations of engagements extended in accordance with paragraphs 4 or 6, neither the statutory auditor or the audit firm nor, where applicable, any members of their networks within the Union shall undertake the statutory audit of the same public-interest entity within the following four-year period.
4. By way of derogation from paragraph 1 and point (b) of paragraph (2), Member States may provide that the maximum durations referred to in the second subparagraph of paragraph 1 and in point (b) of paragraph 2 may be extended to the maximum duration of:
 - (a) 20 years, where a public tendering process for the statutory audit is conducted in accordance with paragraphs 2 to 5 of Article 16 and takes effect upon the expiry of the maximum durations referred to in the second subparagraph of paragraph 1 and in point (b) of paragraph 2; or
 - (b) twenty four years, where, after the expiry of the maximum durations referred to in the second subparagraph of paragraph 1 and in point (b) of paragraph 2, more than one statutory auditor or audit firm is simultaneously engaged, provided that the statutory audit results in the presentation of the joint audit report as referred to in Article 28 of Directive 2006/43/EC.
5. The maximum durations referred to in the second subparagraph of paragraph 1 and in point (b) of paragraph 2 shall be extended only if, upon a recommendation of the audit committee, the administrative or supervisory body, proposes to the general meeting of shareholders or members, in accordance with national law, that the engagement be renewed and that proposal is approved.
6. After the expiry of the maximum durations referred to in the second subparagraph of paragraph 1, in point (b) of paragraph 2, or in paragraph 4, as appropriate, the public-interest entity may, on an exceptional basis, request that the competent authority referred to in Article 20(1) grant an extension to re-appoint the statutory auditor or the audit firm for a further engagement where the conditions in points (a) or (b) of paragraph 4 are met. Such an additional engagement shall not exceed two years.
7. The key audit partners responsible for carrying out a statutory audit shall cease their participation in the statutory audit of the audited entity not later than seven years from the date of their appointment. They shall not participate again in the statutory audit of the audited entity before three years have elapsed following that cessation.

By way of derogation, Member States may require that key audit partners responsible for carrying out a statutory audit cease their participation in the statutory audit of the audited entity earlier than seven years from the date of their respective appointment.

The statutory auditor or the audit firm shall establish an appropriate gradual rotation mechanism with regard to the most senior personnel involved in the statutory audit, including at least the persons who are registered as statutory auditors. The gradual rotation mechanism shall be applied in phases on the basis of individuals rather than of the entire engagement team. It shall be proportionate in view of the scale and the complexity of the activity of the statutory auditor or the audit firm.

The statutory auditor or the audit firm shall be able to demonstrate to the competent authority that such mechanism is effectively applied and adapted to the scale and the complexity of the activity of the statutory auditor or the audit firm.

8. For the purposes of this Article, the duration of the audit engagement shall be calculated as from the first financial year covered in the audit engagement letter in which the statutory auditor or the audit firm has been appointed for the first time for the carrying-out of consecutive statutory audits for the same public-interest entity.

For the purposes of this Article, the audit firm shall include other firms that the audit firm has acquired or that have merged with it.

If there is uncertainty as to the date on which the statutory auditor or the audit firm began carrying out consecutive statutory audits for the public-interest entity, for example due to firm mergers, acquisitions, or changes in ownership structure, the statutory auditor or the audit firm shall immediately report such uncertainties to the competent authority, which shall ultimately determine the relevant date for the purposes of the first subparagraph.

Article 18

Hand-over file

Where a statutory auditor or an audit firm is replaced by another statutory auditor or audit firm, the former statutory auditor or audit firm shall comply with the requirements laid down in Article 23(3) of Directive 2006/43/EC.

Subject to Article 15, the former statutory auditor or audit firm shall also grant the incoming statutory auditor or audit firm access to the additional reports referred to in Article 11 in respect of previous years and to any information transmitted to competent authorities pursuant to Articles 12 and 13.

The former statutory auditor or audit firm shall be able to demonstrate to the competent authority that such information has been provided to the incoming statutory auditor or audit firm.

Article 19

Dismissal and resignation of the statutory auditors or the audit firms

Without prejudice to Article 38(1) of Directive 2006/43/EC, any competent authority designated by a Member State in accordance with Article 20(2) of this Regulation, shall forward the information concerning the dismissal or resignation of the statutory auditor or the audit firm during the engagement and an adequate explanation of the reasons therefor to the competent authority referred to in Article 20(1).

TITLE IV

SURVEILLANCE OF THE ACTIVITIES OF STATUTORY AUDITORS AND AUDIT FIRMS CARRYING OUT STATUTORY AUDIT OF PUBLIC-INTEREST ENTITIES

CHAPTER I

Competent authorities

Article 20

Designation of competent authorities

1. Competent authorities responsible for carrying out the tasks provided for in this Regulation and for ensuring that the provisions of this Regulation are applied shall be designated from amongst the following:

- (a) the competent authority referred to in Article 24(1) of Directive 2004/109/EC;
- (b) the competent authority referred to in point (h) of Article 24(4) of Directive 2004/109/EC;
- (c) the competent authority referred to in Article 32 of Directive 2006/43/EC.

2. By way of derogation from paragraph 1, Member States may decide that the responsibility for ensuring that all or part of the provisions of Title III of this Regulation are applied is to be entrusted to, as appropriate, the competent authorities referred to in:

- (a) Article 48 of Directive 2004/39/EC;
- (b) Article 24(1) of Directive 2004/109/EC;
- (c) point (h) of Article 24(4) of Directive 2004/109/EC;
- (d) Article 20 of Directive 2007/64/EC;
- (e) Article 30 of Directive 2009/138/EC;
- (f) Article 4(1) of Directive 2013/36/EU;

or to other authorities designated by national law.

3. Where more than one competent authority has been designated pursuant to paragraphs 1 and 2, those authorities shall be organised in such a manner that their tasks are clearly allocated.

4. Paragraphs 1, 2 and 3 shall be without prejudice to the right of a Member State to make separate legal and administrative arrangements for overseas countries and territories with which that Member State has special relations.

5. The Member States shall inform the Commission of the designation of competent authorities for the purposes of this Regulation.

The Commission shall consolidate this information and make it public.

Article 21

Conditions of independence

The competent authorities shall be independent of statutory auditors and audit firms.

The competent authorities may consult experts, as referred to in point (c) of Article 26(1), for the purpose of carrying out specific tasks and may also be assisted by experts when this is essential for the proper fulfilment of their tasks. In such instances, the experts shall not be involved in any decision-making.

A person shall not be a member of the governing body, or responsible for the decision-making, of those authorities if during his or her involvement or in the course of the three previous years that person:

- (a) has carried out statutory audits;
- (b) held voting rights in an audit firm;
- (c) was member of the administrative, management or supervisory body of an audit firm;
- (d) was a partner, employee of, or otherwise contracted by, an audit firm.

The funding of those authorities shall be secure and free from undue influence by statutory auditors and audit firms.

*Article 22***Professional secrecy in relation to competent authorities**

The obligation of professional secrecy shall apply to all persons who are or have been employed or independently contracted by, or involved in the governance of, competent authorities or by any authority or body to which tasks have been delegated under Article 24 of this Regulation. Information covered by professional secrecy may not be disclosed to any other person or authority except by virtue of the obligations laid down in this Regulation or the laws, regulations or administrative procedures of a Member State.

*Article 23***Powers of competent authorities**

1. Without prejudice to Article 26, in carrying out their tasks under this Regulation, the competent authorities or any other public authorities of a Member State may not interfere with the content of audit reports.
2. Member States shall ensure that the competent authorities have all the supervisory and investigatory powers that are necessary for the exercise of their functions under this Regulation in accordance with the provisions of Chapter VII of Directive 2006/43/EC.
3. The powers referred to in paragraph 2 of this Article shall include, at least, the power to:
 - (a) access data related to the statutory audit or other documents held by statutory auditors or audit firms in any form relevant to the carrying out of their tasks and to receive or take a copy thereof;
 - (b) obtain information related to the statutory audit from any person;
 - (c) carry out on-site inspections of statutory auditors or audit firms;
 - (d) refer matters for criminal prosecution;
 - (e) request experts to carry out verifications or investigations;
 - (f) take the administrative measures, and impose the sanctions referred to in Article 30a of Directive 2006/43/EC.

The competent authorities may use the powers referred to in the first subparagraph only in relation to:

- (a) statutory auditors and audit firms carrying out statutory audit of public-interest entities;
 - (b) persons involved in the activities of statutory auditors and audit firms carrying out statutory audit of public-interest entities;
 - (c) audited public-interest entities, their affiliates and related third parties;
 - (d) third parties to whom the statutory auditors and the audit firms carrying out statutory audit of public-interest entities have outsourced certain functions or activities; and
 - (e) persons otherwise related or connected to statutory auditors and audit firms carrying out statutory audit of public-interest entities.
4. Member States shall ensure that the competent authorities are allowed to exercise their supervisory and investigatory powers in any of the following ways:
 - (a) directly;
 - (b) in collaboration with other authorities;
 - (c) by application to the competent judicial authorities.

5. The supervisory and investigatory powers of competent authorities shall be exercised in full compliance with national law, and in particular, with the principles of respect for private life and the right of defence.

6. The processing of personal data processed in the exercise of the supervisory and investigatory powers pursuant to this Article shall be carried out in accordance with Directive 95/46/EC.

Article 24

Delegation of tasks

1. Member States may delegate or allow the competent authorities referred to in Article 20(1) to delegate any of the tasks required to be undertaken pursuant to this Regulation to other authorities or bodies designated or otherwise authorised by law to carry out such tasks, except for tasks related to:

- (a) the quality assurance system referred to in Article 26;
- (b) investigations referred to in Article 23 of this Regulation and Article 32 of Directive 2006/43/EC arising from that quality assurance system or from a referral by another authority; and
- (c) sanctions and measures as referred to in Chapter VII of Directive 2006/43/EC related to the quality assurance reviews or investigation of statutory audits of public-interest entities.

2. Any execution of tasks by other authorities or bodies shall be the subject of an express delegation by the competent authority. The delegation shall specify the delegated tasks and the conditions under which they are to be carried out.

Where the competent authority delegates tasks to other authorities or bodies, it shall be able to reclaim these competences on a case-by-case basis.

3. The authorities or bodies shall be organised in such a manner that there are no conflicts of interest. The ultimate responsibility for supervising compliance with this Regulation and with the implementing measures adopted pursuant thereto shall lie with the delegating competent authority.

The competent authority shall inform the Commission and the competent authorities of Member States of any arrangement entered into with regard to the delegation of tasks, including the precise conditions governing such delegation.

4. By way of derogation from paragraph 1, Member States may decide to delegate the tasks referred to in point (c) of paragraph 1 to other authorities or bodies designated or otherwise authorised by law to carry out such tasks, when the majority of the persons involved in the governance of the authority or body concerned is independent from the audit profession.

Article 25

Cooperation with other competent authorities at national level

Competent authorities designated pursuant to Article 20(1) and, where appropriate, any authority to whom such a competent authority has delegated tasks shall cooperate at national level with:

- (a) the competent authorities referred to in Article 32(4) of Directive 2006/43/EC;
- (b) the authorities referred to in Article 20(2), whether or not they have been designated competent authorities for the purposes of this Regulation;
- (c) the financial intelligence units and the competent authorities referred to in Articles 21 and 37 of Directive 2005/60/EC.

For the purposes of such cooperation, the obligation of professional secrecy under Article 22 of this Regulation shall apply.

CHAPTER II

Quality assurance, market monitoring, and transparency of competent authorities

Article 26

Quality assurance

1. For the purposes of this Article:

- (a) 'inspections' means quality assurance reviews of statutory auditors and audit firms, which are led by an inspector and which do not constitute an investigation within the meaning of Article 32(5) of Directive 2006/43/EC;
- (b) 'inspector' means a reviewer who meets the requirements set out in point (a) of the first subparagraph of paragraph 5 of this Article and who is employed or otherwise contracted by a competent authority;
- (c) 'expert' means a natural person who has specific expertise in financial markets, financial reporting, auditing or other fields relevant for inspections, including practising statutory auditors.

2. The competent authorities designated under Article 20(1) shall establish an effective system of audit quality assurance.

They shall carry out quality assurance reviews of statutory auditors and audit firms that carry out statutory audits of public-interest entities on the basis of an analysis of the risk and:

- (a) in the case of statutory auditors and audit firms carrying out statutory audits of public-interest entities other than those defined in points (17) and (18) of Article 2 of Directive 2006/43/EC at least every three years; and,
- (b) in cases other than those referred to in point (a), at least every six years.

3. The competent authority shall have the following responsibilities:

- (a) approval and amendment of the inspection methodologies, including inspection and follow-up manuals, reporting methodologies and periodic inspection programmes;
- (b) approval and amendment of inspection reports and follow-up reports;
- (c) approval and assignment of inspectors for each inspection.

The competent authority shall allocate adequate resources to the quality assurance system.

4. The competent authority shall organise the quality assurance system in a manner that is independent of the reviewed statutory auditors and audit firms.

The competent authority shall ensure that appropriate policies and procedures related to the independence and objectivity of the staff, including inspectors, and the management of the quality assurance system are put in place.

5. The competent authority shall comply with the following criteria when appointing inspectors:

- (a) inspectors shall have appropriate professional education and relevant experience in statutory audit and financial reporting combined with specific training on quality assurance reviews;
- (b) a person who is a practising statutory auditor or is employed by or otherwise associated with a statutory auditor or an audit firm shall not be allowed to act as an inspector;
- (c) a person shall not be allowed to act as an inspector in an inspection of a statutory auditor or an audit firm until at least three years have elapsed since that person ceased to be a partner or employee of that statutory auditor or of that audit firm or to be otherwise associated with that statutory auditor or audit firm;
- (d) inspectors shall declare that there are no conflicts of interest between them and the statutory auditor and the audit firm to be inspected.

By way of derogation from point (b) of paragraph 1, a competent authority may contract experts for carrying out specific inspections when the number of inspectors within the authority is insufficient. The competent authority may also be assisted by experts when this is essential for the proper conduct of an inspection. In such instances, the competent authorities and the experts shall comply with the requirements of this paragraph. Experts shall not be involved in the governance of, or employed or otherwise contracted by professional associations and bodies but may be members of such associations or bodies.

6. The scope of inspections shall at least cover:

- (a) an assessment of the design of the internal quality control system of the statutory auditor or of the audit firm;
- (b) adequate compliance testing of procedures and a review of audit files of public-interest entities in order to verify the effectiveness of the internal quality control system;
- (c) in the light of the findings of the inspection under points (a) and (b) of this paragraph, an assessment of the contents of the most recent annual transparency report published by a statutory auditor or an audit firm in accordance with Article 13.

7. At least the following internal quality control policies and procedures of the statutory auditor or the audit firm shall be reviewed:

- (a) compliance by the statutory auditor or the audit firm with applicable auditing and quality control standards, and ethical and independence requirements, including those set out in Chapter IV of Directive 2006/43/EC and Articles 4 and 5 of this Regulation, as well as relevant laws, regulations and administrative provisions of the Member State concerned;
- (b) the quantity and quality of resources used, including compliance with continuing education requirements as set out in Article 13 of Directive 2006/43/EC;
- (c) compliance with the requirements set out in Article 4 of this Regulation on the audit fees charged.

For the purposes of testing compliance, audit files shall be selected on the basis of an analysis of the risk of a failure to carry out a statutory audit adequately.

Competent authorities shall also periodically review the methodologies used by statutory auditors and audit firms to carry out statutory audits.

In addition to the inspection covered by the first subparagraph, competent authorities shall have the power to perform other inspections.

8. The findings and conclusions of inspections on which recommendations are based, including the findings and conclusions related to a transparency report, shall be communicated to and discussed with the inspected statutory auditor or audit firm before an inspection report is finalised.

Recommendations of inspections shall be implemented by the inspected statutory auditor or audit firm within a reasonable period set by the competent authority. Such period shall not exceed 12 months in the case of recommendations on the internal quality control system of the statutory auditor or of the audit firm.

9. The inspection shall be the subject of a report which shall contain the main conclusions and recommendations of the quality assurance review.

*Article 27***Monitoring market quality and competition**

1. The competent authorities designated under Article 20(1) and the European Competition Network (ECN), as appropriate, shall regularly monitor the developments in the market for providing statutory audit services to public-interest entities and shall in particular assess the following:

- (a) the risks arising from high incidence of quality deficiencies of a statutory auditor or an audit firm, including systematic deficiencies within an audit firm network, which may lead to the demise of any audit firm, the disruption in the provision of statutory audit services whether in a specific sector or across sectors, the further accumulation of risk of audit deficiencies and the impact on the overall stability of the financial sector;
- (b) the market concentration levels, including in specific sectors;
- (c) the performance of audit committees;
- (d) the need to adopt measures to mitigate the risks referred to in point (a).

2. By 17 June 2016, and at least every three years thereafter, each competent authority and the ECN, shall draw up a report on developments in the market for providing statutory audit services to public-interest entities and submit it to the CEAOB, ESMA, EBA, EIOPA and the Commission.

The Commission, following consultations with the CEAOB, ESMA, EBA and EIOPA shall use those reports to draw up a joint report on those developments at Union level. That joint report shall be submitted to the Council, the European Central Bank and the European Systemic Risk Board, as well as, where appropriate, to the European Parliament.

*Article 28***Transparency of competent authorities**

Competent authorities shall be transparent and shall at least publish:

- (a) annual activity reports regarding their tasks under this Regulation;
- (b) annual work programmes regarding their tasks under this Regulation;
- (c) a report on the overall results of the quality assurance system on an annual basis. This report shall include information on recommendations issued, follow-up on the recommendations, supervisory measures taken and sanctions imposed. It shall also include quantitative information and other key performance information on financial resources and staffing, and the efficiency and effectiveness of the quality assurance system;
- (d) the aggregated information on the findings and conclusions of inspections referred to in the first subparagraph of Article 26(8). Member States may require the publication of those findings and conclusions on individual inspections.

*CHAPTER III****Cooperation between competent authorities and relations with the european supervisory authorities****Article 29***Obligation to cooperate**

The competent authorities of the Member States shall cooperate with each other where it is necessary for the purposes of this Regulation, including in cases where the conduct under investigation does not constitute an infringement of any legislative or regulatory provision in force in the Member State concerned.

*Article 30***Establishment of the CEAOB**

1. Without prejudice to the organisation of national auditing oversight, the cooperation between competent authorities shall be organised within the framework of the CEAOB.
2. The CEAOB shall be composed of one member from each Member State who shall be high level representatives from the competent authorities referred to in Article 32(1) of Directive 2006/43/EC, and one member appointed by the ESMA, hereinafter referred to as 'members'.
3. The EBA and EIOPA shall be invited to attend meetings of the CEAOB as observers.
4. The CEAOB shall meet at regular intervals and, where necessary, at the request of the Commission or a Member State.
5. Each member of the CEAOB shall have one vote, except the member appointed by ESMA, who shall not have voting rights. Unless otherwise stated, decisions of the CEAOB shall be taken by simple majority of its members.
6. The Chair of the CEAOB shall be elected from a list of applicants representing the competent authorities referred to in Article 32(1) of Directive 2006/43/EC, or removed, in each case by a two-thirds majority of members. The Chair shall be elected for a four-year term. The Chair may not serve consecutive terms in the same position, but may be re-elected after a cooling-off period of four years.

The Vice-Chair shall be appointed or removed by the Commission.

The Chair and the Vice-Chair shall not have voting rights.

In the event that the Chair resigns or is removed before the end of his or her term of office, the Vice-Chair shall act as Chair until the next meeting of the CEAOB, which shall elect a Chair for the remainder of the term.

7. The CEAOB shall:
 - (a) facilitate the exchange of information, expertise and best practices for the implementation of this Regulation and of Directive 2006/43/EC;
 - (b) provide expert advice to the Commission as well as to the competent authorities, at their request, on issues related to the implementation of this Regulation and of Directive 2006/43/EC;
 - (c) contribute to the technical assessment of public oversight systems of third countries and to the international cooperation between Member States and third countries in that area, as referred to in Articles 46(2) and 47(3) of Directive 2006/43/EC;
 - (d) contribute to the technical examination of international auditing standards, including the processes for their elaboration, with a view to their adoption at Union level;
 - (e) contribute to the improvement of cooperation mechanisms for the oversight of public-interest entities' statutory auditors, audit firms or the networks they belong to;
 - (f) carry out other coordinating tasks in the cases provided for in this Regulation or in Directive 2006/43/EC.
8. For the purposes of carrying out its tasks referred to in point (c) of paragraph 7, the CEAOB shall request the assistance of ESMA, EBA or EIOPA insofar as its request relates to international cooperation between Member States and third countries in the field of statutory audit of public-interest entities supervised by those European Supervisory Authorities. Where such assistance is requested, ESMA, EBA or EIOPA shall assist the CEAOB in its task.
9. For the purposes of carrying out its tasks, the CEAOB may adopt non-binding guidelines or opinions.

The Commission shall publish the guidelines and opinions adopted by the CEAOB.

10. The CEAOB shall assume all existing and on-going tasks, as appropriate, of the European Group of Audit Oversight Bodies (EGAOB) created by Commission Decision 2005/909/EC.
11. The CEAOB may establish sub-groups on a permanent or ad hoc basis to examine specific issues under the terms of reference established by it. Participation in the sub-group discussions may be extended to competent authorities from the countries of the European Economic Area (hereinafter referred to as EEA) in the field of audit oversight or by invitation, on a case-by-case basis, to competent authorities from non-EU/EEA countries, subject to the approval of the CEAOB members. The participation of a competent authority from a non-EU/EEA country may be subject to a limited time period.
12. The CEAOB shall establish a sub-group for the purpose of carrying out the tasks referred to in point (c) of paragraph 7. That sub-group shall be chaired by the member appointed by ESMA pursuant to paragraph 2.
13. At the request of at least three members, or on its own initiative, where this is considered useful and/or necessary, the Chair of the CEAOB may invite experts, including practitioners, with specific competence on a subject on the agenda to participate in the CEAOB's or its sub-group's deliberations as observers. The CEAOB may invite representatives of competent authorities from third countries which are competent in the field of audit oversight to participate in the CEAOB's or its sub-group's deliberations as observers.
14. The Secretariat of the CEAOB shall be provided by the Commission. The expenses of the CEAOB shall be included in the estimates of the Commission.
15. The Chair shall prepare the provisional agenda of each meeting of the CEAOB with due regard to members' written contributions.
16. The Chair or, in his or her absence, the Vice-Chair shall communicate the CEAOB views or positions only with the approval of the members.
17. The CEAOB's discussions shall not be public.
18. The CEAOB shall adopt its rules of procedure.

Article 31

Cooperation with regard to quality assurance reviews, investigations and on-site inspections

1. Competent authorities shall take measures to ensure effective cooperation at Union level in respect of quality assurance reviews.
2. The competent authority of one Member State may request the assistance of the competent authority of another Member State with regard to the quality assurance reviews of statutory auditors or audit firms belonging to a network carrying out significant activities in the requested Member State.
3. Where a competent authority receives a request from a competent authority of another Member State to assist in the quality assurance review of a statutory auditor or an audit firm belonging to a network carrying out significant activities in that Member State, it shall allow the requesting competent authority to assist in such quality assurance review.

The requesting competent authority shall not have the right to access information which might breach national security rules or adversely affect the sovereignty, security or public order of the requested Member State.

4. Where a competent authority concludes that activities contrary to the provisions of this Regulation are being carried out or have been carried out on the territory of another Member State, it shall notify the competent authority of the other Member State of that conclusion in as specific a manner as possible. The competent authority of the other Member State shall take appropriate action. It shall inform the notifying competent authority of the outcome of that action and, to the extent possible, of significant interim developments.

5. A competent authority of one Member State may request that an investigation be carried out by the competent authority of another Member State on the latter's territory.

It may also request that some of its own personnel be allowed to accompany the personnel of the competent authority of that Member State in the course of the investigation, including with regard to on-site inspections.

The investigation or inspection shall be subject throughout to the overall control of the Member State on whose territory it is carried out.

6. The requested competent authority may refuse to act on a request for an investigation to be carried out as provided for in the first subparagraph of paragraph 5, or on a request for its personnel to be accompanied by personnel of a competent authority of another Member State as provided for in the second subparagraph of paragraph 5, in the following cases:

- (a) where such an investigation or on-site inspection might breach national security rules or adversely affect the sovereignty, security or public order of the requested Member State;
- (b) where judicial proceedings have already been initiated in respect of the same actions and against the same persons before the authorities of the requested Member State;
- (c) where a final judgment has already been delivered in respect of the same actions and the same persons by the authorities of the requested Member State.

7. In the event of a quality assurance review or an investigation with cross-border effects, the competent authorities of the Member States concerned may address a joint request to the CEAOB to coordinate the review or investigation.

Article 32

Colleges of competent authorities

1. In order to facilitate the exercise of the tasks referred to in Articles 26, and 31(4) to(6) of this Regulation and Article 30 of Directive 2006/43/EC with regard to specific statutory auditors, audit firms or their networks, colleges may be established with the participation of the competent authority of the home Member State and of any other competent authority, provided that:

- (a) the statutory auditor or the audit firm is providing statutory audit services to public-interest entities within the jurisdiction of the Member States concerned; or
- (b) a branch which is a part of the audit firm is established within the jurisdiction of the Member States concerned.

2. In the case of specific statutory auditors or audit firms, the competent authority of the home Member State shall act as facilitator.

3. With regard to specific networks, competent authorities of the Member States where the network carries out significant activities may request the CEAOB to establish a college with the participation of the requesting competent authorities.

4. Within 15 working days of the establishment of the college of competent authorities with regard to a specific network, its members shall select a facilitator. In the absence of agreement, the CEAOB shall appoint a facilitator from among the members of the college.

Members of the college shall review the selection of the facilitator at least every five years to ensure that the selected facilitator remains the most appropriate occupant of that position.

5. The facilitator shall chair the meetings of the college, coordinate the actions of the college and ensure efficient exchange of information among members of the college.
6. The facilitator shall, within 10 working days of his or her selection, establish written coordination arrangements within the framework of the college regarding the following matters:
- (a) information to be exchanged between competent authorities;
 - (b) cases in which the competent authorities must consult each other;
 - (c) cases in which the competent authorities may delegate supervisory tasks in accordance with Article 33.
7. In the absence of agreement concerning the written coordination arrangements under paragraph 6, any member of the college may refer the matter to the CEAOB. The facilitator shall give due consideration to any advice provided by the CEAOB concerning the written coordination arrangements before agreeing on their final text. The written coordination arrangements shall be set out in a single document containing full reasons for any significant deviation from the advice of the CEAOB. The facilitator shall transmit the written coordination arrangements to the members of the college and to the CEAOB.

Article 33

Delegation of tasks

The competent authority of the home Member State may delegate any of its tasks to the competent authority of another Member State subject to the agreement of that authority. Delegation of tasks shall not affect the responsibility of the delegating competent authority.

Article 34

Confidentiality and professional secrecy in relation to cooperation among competent authorities

1. The obligation of professional secrecy shall apply to all persons who work or who have worked for the bodies involved in the framework of cooperation between competent authorities as referred to in Article 30. Information covered by professional secrecy shall not be disclosed to another person or authority except where such disclosure is necessary for legal proceedings or required by Union or national law.
2. Article 22 shall not prevent bodies involved in the framework of cooperation between competent authorities as referred to in Article 30 and the competent authorities from exchanging confidential information. Information thus exchanged shall be covered by the obligation of professional secrecy, to which persons employed or formerly employed by competent authorities are subject.
3. All the information exchanged under this Regulation between bodies involved in the framework of cooperation between competent authorities as referred to in Article 30, and the competent authorities and other authorities and bodies shall be treated as confidential, except where its disclosure is required by Union or national law.

Article 35

Protection of personal data

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.
2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the CEAOB, ESMA, EBA and EIOPA in the context of this Regulation and of Directive 2006/43/EC.

CHAPTER IV

Cooperation with third-country authorities and with international organisations and bodies*Article 36***Agreement on exchange of information**

1. The competent authorities may conclude cooperation agreements on exchange of information with the competent authorities of third countries only if the information disclosed is subject, in the third countries concerned, to guarantees of professional secrecy which are at least equivalent to those set out in Articles 22 and 34. The competent authorities shall immediately communicate such agreements to the CEAOB and notify the Commission of them.

Information shall only be exchanged under this Article where such exchange of information is necessary for the performance of the tasks of those competent authorities under this Regulation.

Where such exchange of information involves the transfer of personal data to a third country, Member States shall comply with Directive 95/46/EC and the CEAOB shall comply with Regulation (EC) No 45/2001.

2. The competent authorities shall cooperate with the competent authorities or other relevant bodies of third countries regarding the quality assurance reviews and investigations of statutory auditors and audit firms. Upon request by a competent authority, the CEAOB shall contribute to such cooperation and to the establishment of supervisory convergence with third countries.

3. Where the cooperation or exchange of information relates to audit working papers or other documents held by statutory auditors or audit firms, Article 47 of Directive 2006/43/EC shall apply.

4. The CEAOB shall prepare guidelines on the content of the cooperation agreements and exchange of information referred to in this Article.

*Article 37***Disclosure of information received from third countries**

The competent authority of a Member State may disclose the confidential information received from competent authorities of third countries where a cooperation agreement so provides, only if it has obtained the express agreement of the competent authority which has transmitted the information and, where applicable, the information is disclosed only for the purposes for which that competent authority has given its agreement, or where such disclosure is required by Union or national law.

*Article 38***Disclosure of information transferred to third countries**

The competent authority of a Member State shall require that confidential information communicated by it to a competent authority of a third country may be disclosed by that competent authority to third parties or authorities only with the prior express agreement of the competent authority which has transmitted the information, in accordance with its national law and provided that the information is disclosed only for the purposes for which that competent authority of the Member State has given its agreement, or where such disclosure is required by Union or national law or is necessary for legal proceedings in that third country.

*Article 39***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 9 shall be conferred on the Commission for a period of five years from 16 June 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Article 9 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article 9 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 40***Review and reports**

1. The Commission shall review and report on the operation and effectiveness of the system of cooperation between competent authorities within the framework of the CEAOB, referred to in Article 30, in particular as regards the performance of the CEAOB tasks defined in paragraph 7 of that Article.
2. The review shall take into account international developments, particularly in relation to strengthening cooperation with the competent authorities of third countries and contributing to the improvement of cooperation mechanisms for the oversight of statutory auditors and audit firms of public-interest entities belonging to international audit networks. The Commission shall complete its review by 17 June 2019.
3. The report shall be submitted to the European Parliament and to the Council, together with a legislative proposal, if appropriate. That report shall consider the progress made in the field of cooperation between competent authorities within the framework of the CEAOB from the beginning of the operation of that framework and propose further steps to enhance the effectiveness of the cooperation between Member States' competent authorities.
4. By 17 June 2028 the Commission shall submit a report on the application of this Regulation to the European Parliament and to the Council.

*Article 41***Transitional provisions**

1. As from 17 June 2020, a public-interest entity shall not enter into or renew an audit engagement with a given statutory auditor or audit firm if that statutory auditor or audit firm has been providing audit services to that public-interest entity for 20 and more consecutive years at the date of entry into force of this Regulation.

2. As from 17 June 2023, a public-interest entity shall not enter into or renew an audit engagement with a given statutory auditor or audit firm if that statutory auditor or audit firm has been providing audit services to that public-interest entity for 11 and more but less than 20 consecutive years at the date of entry into force of this Regulation.
3. Without prejudice to paragraphs 1 and 2, the audit engagements that were entered into before 16 June 2014 but which are still in place as at 17 June 2016 may remain applicable until the end of the maximum duration referred to in the second subparagraph of Article 17(1) or in point (b) of Article 17(2). Article 17(4) shall apply.
4. Article 16(3) shall only apply to audit engagements after the expiry of the period referred to in the second subparagraph of Article 17(1).

Article 42

National provisions

The Member States shall adopt appropriate provisions to ensure the effective application of this Regulation.

Article 43

Repeal of Commission Decision 2005/909/EC

Commission Decision 2005/909/EC is hereby repealed.

Article 44

Entry into force

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

It shall apply from 17 June 2016.

However, Article 16(6) shall apply from 17 June 2017.

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

Done at Strasbourg, 16 April 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

REGULATION (EU) No 538/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
amending Regulation (EU) No 691/2011 on European environmental economic accounts
(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 338(1) thereof,

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) Decision No 1386/2013/EU of the European Parliament and of the Council ⁽²⁾ provides that the pace of current developments and uncertainties surrounding likely future trends require further steps to ensure that policy in the Union continues to draw on a sound understanding of the state of the environment, of possible response options and their consequences. Instruments should be developed with a view to ensuring the preparation of quality-assured data and indicators and to improving its accessibility. It is important that such data be made available in a comprehensible and accessible form.
- (2) Under Article 10 of Regulation (EU) No 691/2011 of the European Parliament and of the Council ⁽³⁾ the Commission is invited to report to the European Parliament and the Council on the implementation of the Regulation and, if appropriate, to propose the introduction of new environmental economic accounts modules, such as Environmental Protection Expenditure and Revenues (EPER)/Environmental Protection Expenditure Accounts (EPEA), Environmental Goods and Services Sector (EGSS) and Energy Accounts.
- (3) The new modules contribute directly to the Union's policy priorities of green growth and resource efficiency by providing important information on indicators such as market output and employment in the EGSS, national environmental protection expenditure and the use of energy in a NACE breakdown.
- (4) The United Nations Statistical Commission adopted the System of Environmental-Economic Accounting (SEEA) Central Framework as an international statistical standard at its 43rd session in February 2012. The new modules being introduced by this Regulation are fully in line with the SEEA.
- (5) The European Statistical System Committee has been consulted.

⁽¹⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

⁽²⁾ Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' (OJ L 354, 28.12.2013, p. 171).

⁽³⁾ Regulation (EU) No 691/2011 of the European Parliament and of the Council of 6 July 2011 on European environmental economic accounts (OJ L 192, 22.7.2011, p. 1).

- (6) In order to take into account technical and scientific progress and supplement the provisions on energy accounts, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the specification of the list of energy products referred to in Section 3 of Annex VI as contained in the Annex to this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (7) In order to facilitate a uniform application of Annex V as contained in the Annex to this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾. The examination procedure should be used for the adoption of those implementing acts.
- (8) Regulation (EU) No 691/2011 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 691/2011 is amended as follows:

(1) in Article 2, the following points are added:

- '(4) "environmental protection expenditure" means the economic resources devoted by resident units to environmental protection. Environmental protection includes all activities and actions which have as their main purpose the prevention, reduction and elimination of pollution and of any other degradation of the environment. Those activities and actions include all measures taken in order to restore the environment after it has been degraded. Activities which, while beneficial to the environment, primarily satisfy the technical needs or the internal requirements for hygiene or safety and security of an enterprise or other institution are excluded from this definition;
- (5) "environmental goods and services sector" means the production activities of a national economy that generate environmental products (environmental goods and services). Environmental products are products that have been produced for the purpose of environmental protection, as referred to in point (4), and resource management. Resource management includes the preservation, maintenance and enhancement of the stock of natural resources and therefore the safeguarding of those resources against depletion;
- (6) "physical energy flow accounts" means consistent compilations of the physical energy flows into national economies, the flows circulating within the economy and the outputs to other economies or to the environment.;

(2) Article 3 is amended as follows:

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

- '(d) a module for environmental protection expenditure accounts, as set out in Annex IV;
- (e) a module for environmental goods and services sector accounts, as set out in Annex V;
- (f) a module for physical energy flow accounts, as set out in Annex VI.;

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(b) the following paragraphs are added:

'4. The Commission shall be empowered to adopt delegated acts in accordance with Article 9 in order to specify the energy products referred to in Section 3 of Annex VI, based on the lists set out in the Annexes to Regulation (EC) No 1099/2008 of the European Parliament and of the Council (*).

Such delegated acts shall not impose a significant additional burden on the Member States or on the respondents. When establishing and subsequently updating the lists referred to in the first subparagraph, the Commission shall duly justify the actions, using, where appropriate, input from relevant experts on a cost-effectiveness analysis, including an assessment of the burden on respondents and of the production costs.

5. In order to facilitate a uniform application of Annex V, the Commission shall, by 31 December 2015, by means of implementing acts, establish an indicative compendium of environmental goods and services and of the economic activities to be covered by Annex V based on the following categories: environmental specific services, environmental sole purpose products (connected products), adapted goods and environmental technologies. The Commission shall update the compendium where necessary.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 11(2);

(* Regulation (EC) No 1099/2008 of the European Parliament and of the Council of 22 October 2008 on energy statistics (OJ L 304, 14.11.2008, p. 1).'

(3) Article 8(2) is replaced by the following:

'2. For the purposes of obtaining a derogation under paragraph 1 for Annexes I, II and III, the Member State concerned shall present a duly justified request to the Commission by 12 November 2011. For the purposes of obtaining a derogation under paragraph 1 for Annexes IV, V and VI, the Member State concerned shall present a duly justified request to the Commission by 17 September 2014.'

(4) Article 9 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The power to adopt delegated acts referred to in Article 3(3) and (4) shall be conferred on the Commission for a period of five years from 11 August 2011. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.'

(b) paragraph 3 is replaced by the following:

'3. The delegation of power referred to in Article 3(3) and (4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.'

(c) paragraph 5 is replaced by the following:

'5. A delegated act adopted pursuant to Article 3(3) and (4) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.'

(5) Annexes IV, V and VI, as set out in the Annex to this Regulation, are added to Regulation (EU) No 691/2011.

Article 2

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

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

Done at Strasbourg, 16 April 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

ANNEX

ANNEX IV

MODULE FOR ENVIRONMENTAL PROTECTION EXPENDITURE ACCOUNTS**Section 1**

OBJECTIVES

Environmental protection expenditure accounts present data, in a way that is compatible with the data reported under ESA, on the expenditure for environmental protection, i.e. the economic resources devoted by resident units to environmental protection. Such accounts allow for the compiling of national expenditure for environmental protection which is defined as the sum of uses of environmental protection services by resident units, gross fixed capital formation (GFCF) for environmental protection activities, and transfers for environmental protection which are not a counterpart of previous items, less financing by the rest of the world.

The environmental protection expenditure accounts should make use of the already existing information from the national accounts (production and generation of income accounts; GFCF by NACE, supply and use tables; data based on the classification of functions of government), structural business statistics, business register and other sources.

This Annex defines the data to be collected, compiled, transmitted and evaluated for the purposes of environmental protection expenditure accounts by the Member States.

Section 2

COVERAGE

Environmental protection expenditure accounts have the same system boundaries as ESA and show environmental protection expenditure for principal, secondary and ancillary activities. The following sectors are covered:

- general government (including non-profit institutions serving households) and corporations as institutional sectors producing environmental protection services. Specialist producers produce environmental protection services as their principal activity,
- households, general government and corporations as consumers of environmental protection services,
- the rest of the world as beneficiary, or origin, of transfers for environmental protection.

Section 3

LIST OF CHARACTERISTICS

Member States shall produce environmental protection expenditure accounts according to the following characteristics which are defined in accordance with ESA:

- output of environmental protection services. Market output, non-market output and output of ancillary activities are distinguished,
- intermediate consumption of environmental protection services by specialist producers,
- imports and exports of environmental protection services,
- valued added tax (VAT) and other taxes less subsidies on products on environmental protection services,
- gross fixed capital formation and acquisitions less disposals of non-financial non-produced assets for the production of environmental protection services,
- final consumption of environmental protection services,
- environmental protection transfers (received/paid).

All data shall be reported in million national currency.

Section 4

FIRST REFERENCE YEAR, FREQUENCY AND TRANSMISSION DEADLINES

1. Statistics shall be compiled and transmitted on a yearly basis.
2. Statistics shall be transmitted within 24 months of the end of the reference year.
3. In order to meet user needs for complete and timely datasets, the Commission (Eurostat) shall produce, as soon as sufficient country data becomes available, estimates for the EU-28 totals for the main aggregates of this module. The Commission (Eurostat) shall, wherever possible, produce and publish estimates for data that have not been transmitted by Member States within the deadline specified in point 2.
4. The first reference year is 2015.
5. In the first transmission of data, Member States shall include annual data from 2014 to the first reference year.
6. In each subsequent data transmission to the Commission, Member States shall provide annual data for the years $n - 2$, $n - 1$ and n , where n is the reference year. Member States may provide any available data for the years preceding 2014.

Section 5

REPORTING TABLES

1. For the characteristics referred to in Section 3, data shall be reported in a breakdown by:
 - type of producers/consumers of environmental protection services as defined in Section 2,
 - classes of the classification of environmental protection activities (CEPA) grouped as follows:
 - For general government activities and for environmental protection transfers:
 - CEPA 2
 - CEPA 3
 - Sum of CEPA 1, CEPA 4, CEPA 5 and CEPA 7
 - CEPA 6
 - Sum of CEPA 8 and CEPA 9
 - For ancillary activities of corporations:
 - CEPA 1
 - CEPA 2
 - CEPA 3
 - Sum of CEPA 4, CEPA 5, CEPA 6, CEPA 7, CEPA 8 and CEPA 9
 - For corporations as secondary and specialist producers:
 - CEPA 2
 - CEPA 3
 - CEPA 4
 - For households as consumers:
 - CEPA 2
 - CEPA 3

— The following NACE codes for the ancillary production of environmental protection services: NACE Rev. 2 B, C, D, Division 36. Data for section C shall be presented by divisions. Divisions 10-12, 13-15 and 31-32 shall be grouped together. Member States which, under Regulation (EC) No 295/2008 of the European Parliament and of the Council ⁽¹⁾ (as regards the definitions of characteristics, the technical format for the transmission of data, the double reporting requirements for NACE Rev. 1.1 and NACE Rev. 2 and derogations to be granted for structural business statistics), are not obliged to collect environmental protection expenditure data for one or more of these NACE codes, do not need to provide data for these NACE codes.

2. The CEPA classes referred to in point 1 are as follows:

CEPA 1 — Protection of ambient air and climate

CEPA 2 — Wastewater management

CEPA 3 — Waste management

CEPA 4 — Protection and remediation of soil, groundwater and surface water

CEPA 5 — Noise and vibration abatement

CEPA 6 — Protection of biodiversity and landscapes

CEPA 7 — Protection against radiation

CEPA 8 — Environmental research and development

CEPA 9 — Other environmental protection activities.

Section 6

MAXIMUM DURATION OF THE TRANSITIONAL PERIODS

For the implementation of the provisions of this Annex, the maximum duration of the transitional period is 2 years from the first transmission deadline.

ANNEX V

MODULE FOR ENVIRONMENTAL GOODS AND SERVICES SECTOR ACCOUNTS

Section 1

OBJECTIVES

Statistics on environmental goods and services record and present data on national economy production activities that generate environmental products in a way that is compatible with the data reported under ESA.

The environmental goods and services sector accounts should make use of the already existing information from the national accounts, structural business statistics, business register and other sources.

This Annex defines the data to be collected, compiled, transmitted and evaluated for environmental goods and services accounts, by the Member States.

Section 2

COVERAGE

The environmental goods and services sector has the same system boundaries as ESA and consists of all environmental goods and services that are created within the production boundary. ESA defines production as the activity carried out under the control and responsibility of an institutional unit that uses inputs of labour, capital and goods and services to produce goods and services.

⁽¹⁾ Regulation (EC) No 295/2008 of the European Parliament and of the Council of 11 March 2008 concerning structural business statistics (OJ L 97, 9.4.2008, p. 13).

Environmental goods and services fall within the following categories: environmental specific services, environmental sole purpose products (connected products), adapted goods and environmental technologies.

Section 3

LIST OF CHARACTERISTICS

Member States shall produce statistics on the environmental goods and services sector according to the following characteristics:

- market output, of which:
 - exports,
- value added of market activities,
- employment of market activities.

All data shall be reported in million national currency, except for the characteristic “employment” for which the reporting unit shall be “full time equivalent”.

Section 4

FIRST REFERENCE YEAR, FREQUENCY AND TRANSMISSION DEADLINES

1. Statistics shall be compiled and transmitted on a yearly basis.
2. Statistics shall be transmitted within 24 months of the end of the reference year.
3. In order to meet user needs for complete and timely datasets, the Commission (Eurostat) shall produce, as soon as sufficient country data becomes available, estimates for the EU-28 totals for the main aggregates of this module. The Commission (Eurostat) shall, wherever possible, produce and publish estimates for data that have not been transmitted by Member States within the deadline specified in point 2.
4. The first reference year is 2015.
5. In the first transmission of data, Member States shall include annual data from 2014 to the first reference year.
6. In each subsequent data transmission to the Commission, Member States shall provide annual data for the years $n - 2$, $n - 1$ and n , where n is the reference year. Member States may provide any available data for the years preceding 2014.

Section 5

REPORTING TABLES

1. For the characteristics referred to in Section 3, data shall be reported cross-classified by:
 - classification of economic activities, NACE Rev. 2 (A*21 aggregation level as set out in ESA),
 - CEPA classes and the classification of resource management activities (CReMA) grouped as follows:
 - CEPA 1
 - CEPA 2
 - CEPA 3
 - CEPA 4
 - CEPA 5
 - CEPA 6

- Sum of CEPA 7, CEPA 8 and CEPA 9
 - CReMA 10
 - CReMA 11
 - CReMA 13
 - CReMA 13A
 - CReMA 13B
 - CReMA 13C
 - CReMA 14
 - Sum of CReMA 12, CReMA 15 and CReMA 16
2. The CEPA classes referred to in point 1 are as set out in Annex IV. The CReMA classes referred to in point 1 are as follows:

CReMA 10 — Management of water

CReMA 11 — Management of forest resources

CReMA 12 — Management of wild flora and fauna

CReMA 13 — Management of energy resources:

- CReMA 13A — Production of energy from renewable resources

- CReMA 13B — Heat/energy saving and management

- CReMA 13C — Minimisation of the use of fossil energy as raw materials

CReMA 14 — Management of minerals

CReMA 15 — Research and development activities for resource management

CReMA 16 — Other resource management activities

Section 6

MAXIMUM DURATION OF THE TRANSITIONAL PERIODS

For the implementation of the provisions of this Annex, the maximum duration of the transitional period is 2 years from the first transmission deadline.

ANNEX VI

MODULE FOR PHYSICAL ENERGY FLOW ACCOUNTS

Section 1

OBJECTIVES

Physical energy flow accounts present data on the physical flows of energy expressed in terajoules in a way that is fully compatible with the ESA. Physical energy flow accounts record energy data in relation to the economic activities of resident units of national economies in a breakdown by economic activity. They present the supply and use of natural energy inputs, energy products and energy residuals. Economic activities comprise production, consumption, and accumulation.

This Annex defines the data to be collected, compiled, transmitted and evaluated for physical energy flow accounts by the Member States.

Section 2

COVERAGE

Physical energy flow accounts have the same system boundaries as ESA and are also based on the residence principle.

In accordance with ESA, a unit is said to be a resident unit of a country when it has a centre of economic interest in the economic territory of that country, that is, when it engages for an extended period (1 year or more) in economic activities in that territory.

Physical energy flow accounts record physical energy flows arising from the activities of all resident units, regardless of where these flows actually occur geographically.

Physical energy flow accounts record the physical flows of energy from the environment to the economy, within the economy, and from the economy back to the environment.

Section 3

LIST OF CHARACTERISTICS

Member States shall produce physical energy flow accounts according to the following characteristics:

- the physical energy flows grouped into three generic categories:
 - (i) natural energy inputs,
 - (ii) energy products,
 - (iii) energy residuals,
- the origin of the physical energy flows, grouped into five categories: production, consumption, accumulation, rest of the world and environment,
- the destination of the physical flows, grouped into the same five categories as the origin of the physical energy flows.

All data shall be reported in terajoules.

Section 4

FIRST REFERENCE YEAR, FREQUENCY AND TRANSMISSION DEADLINES

1. Statistics shall be compiled and transmitted on a yearly basis.
2. Statistics shall be transmitted within 21 months of the end of the reference year.
3. In order to meet user needs for complete and timely datasets, the Commission (Eurostat) shall produce, as soon as sufficient country data becomes available, estimates for the EU-28 totals for the main aggregates of this module. The Commission (Eurostat) shall, wherever possible, produce and publish estimates for data that have not been transmitted by Member States within the deadline specified in point 2.
4. The first reference year is 2015.
5. In the first transmission of data, Member States shall include annual data from 2014 to the first reference year.
6. In each subsequent data transmission to the Commission, Member States shall provide annual data for the years $n - 2$, $n - 1$ and n , where n is the reference year. Member States may provide any available data for the years preceding 2014.

Section 5

REPORTING TABLES

1. For the characteristics referred to in Section 3, the following data shall be reported in physical units:
 - Supply table for energy flows. This table records the supply of natural energy inputs, energy products, and energy residuals (row-wise) by origin, i.e. “supplier” (column-wise).
 - Use table for energy flows. This table records the use of natural energy inputs, energy products, and energy residuals (row-wise) by destination, i.e. “user” (column-wise).
 - Table of emission-relevant use of energy flows. This table records the emission-relevant use of natural energy inputs and energy products (row-wise) by the using and emitting unit (column-wise).
 - Bridge table showing the various elements which make up the difference between the energy accounts and the energy balances.
2. The supply and use tables of energy flows (including emission-relevant flows) have a common layout in terms of rows and columns.
3. The columns denote the origins (supply) or destinations (use) of the physical flows. The columns are grouped into five categories:
 - “Production” relates to the production of goods and services. Production activities are classified according to NACE Rev. 2 and data is reported in A*64 aggregation level.
 - “Consumption” activities are presented in total and also divided into three sub-classes (transport, heating/cooling, other) for private households’ final consumption.
 - “Accumulation” refers to the changes in stocks of energy products within the economy.
 - “Rest of the world” records the flows of imported and exported products.
 - “Environment” records the origin of natural input flows and the destination of residual flows.
4. The rows describe the type of physical flows classified in the first indent of Section 3.
5. The classification of natural energy inputs, energy products, and energy residuals is as follows:
 - natural energy inputs are grouped into non-renewable natural energy inputs and renewable natural energy inputs,
 - energy products are grouped according to the classification used in European energy statistics,
 - energy residuals include waste (without monetary value); losses during extraction/abstraction, distribution/transport, transformation/conversion and storage; as well as balancing items to balance the supply and use tables.
6. The “bridge” from the residence principle indicator to the territory-based indicator is presented for the entire national economy (no breakdown by industries) and is obtained as follows:

total energy use by resident units:

- energy use by resident units abroad
- + energy use by non-residents on the territory
- + statistical differences
- = gross inland energy consumption (territory-based)

Section 6

MAXIMUM DURATION OF THE TRANSITIONAL PERIODS

For the implementation of the provisions of this Annex, the maximum duration of the transitional period is 2 years from the first transmission deadline.'

REGULATION (EU) No 539/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on imports of rice originating in Bangladesh and repealing Council Regulation (EEC) No 3491/90

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 207 thereof,

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) In the context of the Uruguay Round, the Union undertook to offer preferential import arrangements for rice originating in the least-developed countries. One of the countries to which that offer was addressed, Bangladesh, indicated its interest in the development of trade in rice. To that end, Council Regulation (EEC) No 3491/90 ⁽²⁾ was adopted.
- (2) Regulation (EEC) No 3491/90 confers powers on the Commission in order to implement some of its provisions. As a consequence of the entry into force of the Treaty of Lisbon, those powers should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU). For the sake of clarity, it is appropriate to repeal Regulation (EEC) No 3491/90 and to replace it with this Regulation.
- (3) The preferential import arrangement involves a reduction in the import duty within the limit of a certain quantity of husked rice. The equivalent quantities at stages of milling other than the husked-rice stage should be calculated in accordance with Commission Regulation (EC) No 1312/2008 ⁽³⁾.
- (4) In order to fix the import duties applicable to rice originating in Bangladesh imported under this Regulation, account should be taken of the relevant provisions of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽⁴⁾.
- (5) To ensure that the advantages of the preferential import arrangement are limited to rice originating in Bangladesh, a certificate of origin should be issued.
- (6) In order to supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the establishment of rules making participation in the arrangement conditional upon the lodging of a security, in accordance with Article 66 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽⁵⁾. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (7) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers, save where explicitly provided otherwise, should be exercised in

⁽¹⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

⁽²⁾ Council Regulation (EEC) No 3491/90 of 26 November 1990 on imports of rice originating in Bangladesh (OJ L 337, 4.12.1990, p. 1).

⁽³⁾ Commission Regulation (EC) No 1312/2008 of 19 December 2008 fixing the conversion rates, the processing costs and the value of the by-products for the various stages of rice processing (OJ L 344, 20.12.2008, p. 56).

⁽⁴⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

⁽⁵⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾. However, where the suspension of the preferential import arrangement becomes necessary, the Commission should be allowed to adopt implementing acts without applying that Regulation.

- (8) This Regulation is part of the Union's common commercial policy, which must be consistent with the objectives of the Union policy in the field of development cooperation as set out in Article 208 TFEU, in particular the eradication of poverty and the promotion of sustainable development and good governance in developing countries. Therefore, this Regulation should also comply with World Trade Organization (WTO) requirements, in particular with the Decision on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries (the 'Enabling Clause'), adopted under the General Agreement on Tariffs and Trade in 1979, under which WTO Members may accord differential and more favourable treatment to developing countries.
- (9) This Regulation is also based on the recognition of the right of small farmers and rural workers to a decent income and to a safe and healthy working environment as a fundamental objective of trade preferences that are granted to developing countries and the least-developed countries in particular. The Union aims to define and pursue common policies and actions in order to foster the sustainable economic, social and environmental development of developing countries, with the primary aim of eradicating poverty. In this context, the ratification and effective implementation of core international conventions on human rights and labour rights, environmental protection and good governance, notably those laid down in Annex VIII to Regulation (EU) No 978/2012 of the European Parliament and of the Council ⁽²⁾, are essential to support progress towards sustainable development, as reflected by the special incentive arrangement providing for additional tariff preferences under that Regulation,

HAVE ADOPTED THIS REGULATION:

Article 1

Scope

1. This Regulation establishes a preferential import arrangement for imports of rice originating in Bangladesh falling within CN codes 1006 10 (excluding CN code 1006 10 10), 1006 20 and 1006 30.
2. The preferential import arrangement shall be limited to a quantity equivalent to 4 000 tonnes of husked rice per calendar year.

The quantities at stages of milling other than the husked-rice stage shall be converted using the conversion rates fixed in Article 1 of Regulation (EC) No 1312/2008.

3. The Commission shall adopt an implementing act suspending the application of the preferential import arrangement provided for in paragraph 1 of this Article once it ascertains that, during the year in progress, imports qualifying under the said arrangement have reached the quantity indicated in paragraph 2 of this Article. That implementing act shall be adopted without applying the procedure referred to in Article 6(2).

Article 2

Import duty

1. Within the limit of the quantity laid down in Article 1(2), the import duty on rice shall be equal to the following:
 - (a) for paddy rice falling within CN codes 1006 10, with the exception of CN code 1006 10 10, the customs duties fixed in the Common Customs Tariff less 50 % and less a further EUR 4,34;
 - (b) for husked rice falling within CN code 1006 20, the duty fixed in accordance with Article 183 of Regulation (EU) No 1308/2013 less 50 % and less a further EUR 4,34;
 - (c) for semi-milled and milled rice falling within CN code 1006 30, the duty fixed in accordance with Article 183 of Regulation (EU) No 1308/2013 less EUR 16,78, less a further 50 % and less an additional EUR 6,52.
2. Paragraph 1 shall apply subject to the condition that the competent authority of Bangladesh has issued a certificate of origin.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽²⁾ Regulation (EU) No 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No 732/2008 (OJ L 303, 31.10.2012, p. 1).

*Article 3***Delegated powers**

In order to ensure the reliability and the efficiency of the preferential import arrangement, the Commission shall be empowered to adopt delegated acts in accordance with Article 4 laying down rules making the participation in the preferential import arrangement established in Article 1 conditional upon the lodging of a security.

*Article 4***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 3 shall be conferred on the Commission for a period of five years from 28 May 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Article 3 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article 3 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 5***Implementing powers**

The Commission shall adopt implementing acts determining the necessary measures in respect of:

- (a) the administrative method to be used for the management of the preferential import arrangement;
- (b) the means for determining the origin of the product covered by the preferential import arrangement;
- (c) the form and period of validity of the certificate of origin referred to in Article 2(2);
- (d) the period of validity of the import licences, where appropriate;
- (e) the amount of the security required to be lodged in accordance with Article 3;
- (f) the notifications to be made to the Commission by Member States.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 6(2).

*Article 6***Committee procedure**

1. The Commission shall be assisted by the Committee for the Common Organisation of the Agricultural Markets established by Article 229(1) of Regulation (EU) No 1308/2013. 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.
3. Where the opinion of the committee referred to in paragraph 1 is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or at least a quarter of committee members so request.

Article 7

Repeal

Regulation (EEC) No 3491/90 is repealed.

References to Regulation (EEC) No 3491/90 shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex to this Regulation.

Article 8

Entry into force

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

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

Done at Strasbourg, 16 April 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

ANNEX

Correlation table

Regulation (EEC) No 3491/90	This Regulation
Article 1	Article 2
Article 2(1)	Article 1(2)
Article 2(2)	Article 1(3)
Article 3	Articles 3 to 6

STATEMENT ON DELEGATED ACTS

In the context of Regulation (EU) No 539/2014 of the European Parliament and of the Council of 16 April 2014 on imports of rice originating in Bangladesh and repealing Council Regulation (EEC) No 3491/90 ⁽¹⁾, the Commission recalls the commitment it has taken in paragraph 15 of the Framework Agreement on relations between the European Parliament and the European Commission to provide to the Parliament full information and documentation on its meetings with national experts within the framework of its work on the preparation of delegated acts.

⁽¹⁾ See page 125 of this Official Journal.

**REGULATION (EU) No 540/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014**

**on the sound level of motor vehicles and of replacement silencing systems, and amending
Directive 2007/46/EC and repealing Directive 70/157/EEC**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) In accordance with Article 26(2) of the Treaty on the Functioning of the European Union (TFEU), the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is to be ensured. To that end, a comprehensive EU type-approval system for motor vehicles is in place. The technical requirements for the EU type-approval of motor vehicles and their silencing systems with regard to permissible sound levels should be harmonised to avoid the adoption of requirements that differ from one Member State to another, and to ensure the proper functioning of the internal market while, at the same time, providing for a high level of environmental protection and public safety, a better quality of life and health, and taking account of road vehicles as a significant source of noise in the transport sector.
- (2) EU type-approval requirements already apply in the context of Union law regulating various aspects of the performance of motor vehicles, such as CO₂ emissions from cars and light commercial vehicles, pollutant emissions and safety standards. The technical requirements applicable pursuant to this Regulation should be developed in a way that ensures a consistent approach throughout that Union law, taking into account all relevant noise factors.
- (3) Traffic noise harms health in numerous ways. Protracted noise-related stress can exhaust human physical reserves, disrupt the regulatory capacity of organ functions and hence limit their effectiveness. Traffic noise is a potential risk factor for the development of medical conditions and incidents such as high blood pressure and heart attacks. The effects of traffic noise should be further researched in the same manner as provided for in Directive 2002/49/EC of the European Parliament and of the Council ⁽³⁾.
- (4) Council Directive 70/157/EEC ⁽⁴⁾ harmonised the different technical requirements of Member States relating to the permissible sound level of motor vehicles and of their exhaust systems for the purpose of the establishment and operation of the internal market. For the purposes of the proper functioning of the internal market and in order to ensure a uniform and consistent application throughout the Union, it is appropriate to replace that Directive by this Regulation.

⁽¹⁾ OJ C 191, 29.6.2012, p. 76.

⁽²⁾ Position of the European Parliament of 6 February 2013 (not yet published in the Official Journal) and position of the Council at first reading of 20 February 2014 (not yet published in the Official Journal). Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal).

⁽³⁾ Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise (OJ L 189, 18.7.2002, p. 12).

⁽⁴⁾ Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 42, 23.2.1970, p. 16).

- (5) This Regulation constitutes a separate Regulation in the context of the type-approval procedure under Directive 2007/46/EC of the European Parliament and of the Council ⁽¹⁾. Accordingly, Annexes IV, VI and XI to that Directive should be amended.
- (6) Directive 70/157/EEC refers to Regulation No 51 of the United Nations Economic Commission for Europe (UNECE) on noise emissions ⁽²⁾, which specifies the test method for noise emissions, and to UNECE Regulation No 59 on uniform provisions concerning the approval of replacement silencing systems ⁽³⁾. As a Contracting Party to the Agreement of UNECE of 20 March 1958 concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ⁽⁴⁾, the Union has decided to apply those Regulations.
- (7) Since its adoption, Directive 70/157/EEC has been substantially amended several times. The most recent reduction of sound level limits for motor vehicles, introduced in 1995, did not have the effects expected. Studies showed that the test method used under that Directive no longer reflected real life driving behaviour in urban traffic. In particular, as pointed out in the Green Paper on the Future Noise Policy of 4 November 1996, the contribution of tyre-rolling noise to total noise emissions was underestimated in the test method.
- (8) This Regulation should therefore introduce a different test method from that laid down in Directive 70/157/EEC. The new method should be based on the test method published by the UNECE Working Party on Noise (GRB) in 2007 which incorporated a 2007 version of the standard ISO 362. The results of monitoring of both the old and the new test methods were submitted to the Commission.
- (9) The new test method is considered to be representative for sound levels during normal traffic conditions, but it is less representative for sound levels under worst case conditions. Therefore, it is necessary to lay down in this Regulation additional sound emission provisions. Those provisions should establish preventive requirements intended to cover driving conditions of the vehicle in real traffic outside the type-approval driving cycle and to prevent cycle beating. Those driving conditions are environmentally relevant and it is important to ensure that the sound emission of a vehicle under street-driving conditions does not differ significantly from what can be expected from the type-approval test result for the specific vehicle.
- (10) This Regulation should also further reduce sound level limits. It should take account of the new stricter noise requirements for motor vehicle tyres laid down in Regulation (EC) No 661/2009 of the European Parliament and of the Council ⁽⁵⁾. Studies highlighting the annoyance and adverse health effects resulting from road traffic noise and the associated costs and benefits should also be taken into account.
- (11) The overall limit values should be reduced with regard to all noise sources of motor vehicles including the air intake over the power train and the exhaust, taking into account the tyre contribution to noise reduction referred to in Regulation (EC) No 661/2009.
- (12) Chapter III of Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽⁶⁾, in accordance with which Member States are required to carry out market surveillance and control products entering the Union market, applies to the products covered by this Regulation.

⁽¹⁾ Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1).

⁽²⁾ Regulation No 51 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of motor vehicles having at least four wheels with regard to their noise emissions (OJ L 137, 30.5.2007, p. 68).

⁽³⁾ Regulation No 59 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of replacement silencing systems (OJ L 326, 24.11.2006, p. 43).

⁽⁴⁾ Council Decision 97/836/EC of 27 November 1997 with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement') (OJ L 346, 17.12.1997, p. 78).

⁽⁵⁾ Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJ L 200, 31.7.2009, p. 1).

⁽⁶⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

- (13) Noise is a multifaceted issue with multiple sources and factors that influence the sound perceived by people and the impact of that sound upon them. Vehicle sound levels are partially dependent on the environment in which the vehicles are used, in particular the quality of the road infrastructure, and therefore a more integrated approach is required. Directive 2002/49/EC requires strategic noise maps to be drawn up periodically as regards, inter alia, major roads. The information presented in those maps could form the basis of future research work regarding environmental noise in general, and road surface noise in particular, as well as best practice guides on technological road quality development and a classification of road surface types, if appropriate.
- (14) The Sixth Community Environment Action Programme ⁽¹⁾ set out the framework for environmental policy-making in the Union for the period 2002-2012. That programme called for actions in the field of noise pollution to substantially reduce the number of people regularly affected by long-term average levels of noise, particularly from traffic.
- (15) Technical measures to reduce the sound level of motor vehicles have to comply with a set of competing requirements, such as those of reducing noise and pollutant emissions and improving safety whilst keeping the vehicle in question as cheap and efficient as possible. In attempting to comply with all those requirements equally and strike a balance between them, the vehicle industry all too often runs up against the limits of what is currently technically feasible. Vehicle designers have repeatedly managed to push those limits back by using new, innovative materials and methods. Union law should set a clear framework for innovation that can be achieved in a realistic timeframe. This Regulation establishes such a framework and thus provides an immediate incentive for innovation in keeping with the needs of society, whilst in no way restricting the economic freedom that is vital to the industry.
- (16) Noise pollution is primarily a local problem, but one which calls for a Union-wide solution. The first step in any sustainable noise emissions policy should be to devise measures to reduce sound levels at source. Since the target of this Regulation is the noise source that motor vehicles represent, and given that that noise source is by definition a mobile one, national measures alone are not sufficient.
- (17) The provision of information on sound emissions to consumers and public authorities has the potential to influence purchasing decisions and accelerate the transition to a quieter vehicle fleet. Accordingly, manufacturers should provide information on sound levels of vehicles at the point of sale and in technical promotional material. A label, comparable to the labels used for information on CO₂ emissions, fuel-consumption and tyre-noise, should inform consumers about the sound emissions of a vehicle. The Commission should undertake an impact assessment on the labelling conditions applicable to air and noise pollution levels and on consumer information. That impact assessment should take into account the different types of vehicles covered by this Regulation (including pure electric vehicles) as well as the effect that such labelling could have on the vehicle industry.
- (18) In order to reduce road traffic noise, public authorities should be able to put in place measures and incentives to encourage the use of quieter vehicles.
- (19) Environmental benefits from hybrid electric and pure electric vehicles have resulted in a substantial reduction of the noise emitted by such vehicles. That reduction has removed an important source of an audible signal that is relied upon by blind and visually impaired pedestrians and cyclists, amongst other road users, to become aware of the approach, presence or departure of those vehicles. As a consequence, industry is developing Acoustic Vehicle Alerting Systems (AVAS) to compensate for this lack of audible signal in hybrid electric and pure electric vehicles. The performance of such AVAS fitted to vehicles should be harmonised. In developing of those AVAS consideration should be given to the overall impact on noise in communities.
- (20) The Commission should examine the potential of active safety systems in more silent vehicles such as hybrid electric and pure electric vehicles in order to better serve the objective of improving the safety of vulnerable road users in urban areas, such as blind, visually impaired and aurally challenged pedestrians, cyclists and children.
- (21) Vehicle sound levels have a direct impact on the quality of life of Union citizens, in particular in urban areas in which there is little or no electric or underground public transport provision or cycling or walking infrastructure. The target of doubling the number of public transport users that the European Parliament set in its resolution of 15 December 2011 on the Roadmap to a Single European Transport Area - Towards a competitive and resource

⁽¹⁾ Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme (OJ L 242, 10.9.2002, p. 1).

efficient transport system ⁽¹⁾ should also be taken into account. The Commission and the Member States should, in accordance with the subsidiarity principle, promote public transport, walking and cycling, with a view to reducing noise pollution in urban areas.

- (22) A vehicle's sound level is partially dependent on how it is used and how well it is maintained following its purchase. Therefore, steps should be taken to raise public awareness in the Union of the importance of adopting a smooth driving style and keeping within the speed limits in force in each Member State.
- (23) In order to simplify the type-approval legislation of the Union, in line with the 2007 recommendations of the CARS 21 Report, it is appropriate to base this Regulation on UNECE Regulations No 51, with regard to the test method, and No 59 with regard to replacement silencing systems.
- (24) To enable the Commission to adapt certain requirements of Annexes I, IV, VIII and X to this Regulation to technical progress, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the amendment of the provisions in those Annexes related to the test methods and sound levels. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (25) Since the objective of this Regulation, namely to lay down administrative and technical requirements for the EU type-approval of all new vehicles with regard to their sound level and of replacement silencing systems and components thereof type-approved as separate technical units and intended for those vehicles, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (26) As a consequence of the application of the new regulatory framework laid down pursuant to this Regulation, Directive 70/157/EEC should be repealed,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes the administrative and technical requirements for the EU type-approval of all new vehicles of the categories referred to in Article 2 with regard to their sound level, and of replacement silencing systems and components thereof type-approved as separate technical units designed and constructed for vehicles of categories M₁ and N₁ with a view to facilitating their registration, sale and entry into service within the Union.

Article 2

Scope

This Regulation shall apply to vehicles of categories M₁, M₂, M₃, N₁, N₂ and N₃, as defined in Annex II to Directive 2007/46/EC, and to replacement silencing systems and components thereof type-approved as separate technical units designed and constructed for vehicles of categories M₁ and N₁.

Article 3

Definitions

For the purposes of this Regulation, the definitions laid down in Article 3 of Directive 2007/46/EC apply.

In addition, the following definitions also apply:

- (1) 'type-approval of a vehicle' means the procedure referred to in Article 3 of Directive 2007/46/EC with regard to sound levels;

⁽¹⁾ OJ C 168 E, 14.6.2013, p. 72.

- (2) 'vehicle type' means a category of motor vehicles which do not differ in essential respects such as:
- (a) for vehicles of categories M_1 , $M_2 \leq 3\,500$ kg, N_1 tested in accordance with point 4.1.2.1 of Annex II:
- (i) the shape or materials of the bodywork (particularly the engine compartment and its soundproofing);
 - (ii) the type of engine (e.g. positive or compression ignition, two- or four-stroke, reciprocating or rotary piston), number and capacity of cylinders, number and type of carburettors or injection system, arrangement of valves, or the type of electric motor;
 - (iii) rated maximum net power and corresponding engine speed(s); however if the rated maximum power and the corresponding engine speed differs only due to different engine mappings, those vehicles may be regarded as of the same type;
 - (iv) the silencing system;
- (b) for vehicles of categories $M_2 > 3\,500$ kg, M_3 , N_2 , N_3 tested in accordance with point 4.1.2.2 of Annex II:
- (i) the shape or materials of the bodywork (particularly the engine compartment and its soundproofing);
 - (ii) the type of engine (e.g. positive or compression ignition, two- or four-stroke, reciprocating or rotary piston), number and capacity of cylinders, type of injection system, arrangement of valves, rated engine speed (S), or the type of electric motor;
 - (iii) vehicles having the same type of engine and/or different overall gear ratios may be regarded as vehicles of the same type.

However, if the differences in point (b) provide for different target conditions, as described in point 4.1.2.2 of Annex II, those differences shall be regarded as a change of type;

- (3) 'technically permissible maximum laden mass' (M) means the maximum mass allocated to a vehicle on the basis of its construction features and its design performance; the technically permissible laden mass of a trailer or of a semi-trailer includes the static mass transferred to the towing vehicle when coupled;
- (4) 'rated maximum net power' (P_n) means the engine power expressed in kW and measured by the UNECE method pursuant to UNECE Regulation No 85 ⁽¹⁾.

If the rated maximum net power is reached at several engine speeds, the highest engine speed shall be used;

- (5) 'standard equipment' means the basic configuration of a vehicle including all features that are fitted without giving rise to any further specifications on configuration or equipment level but equipped with all the features required under the regulatory acts mentioned in Annex IV or Annex XI to Directive 2007/46/EC;
- (6) 'mass of the driver' means a mass rated at 75 kg located at the driver's seating reference point;
- (7) 'mass of a vehicle in running order' (m_{r0}) means
- (a) in the case of a motor vehicle:

the mass of the vehicle, with its fuel tank(s) filled to at least 90 % of its or their capacity/ies, including the mass of the driver, the fuel and liquids, fitted with the standard equipment in accordance with the manufacturer's specifications and, where they are fitted, the mass of the bodywork, the cabin, the coupling and the spare wheel(s) as well as the tools;

⁽¹⁾ Regulation No 85 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of internal combustion engines or electric drive trains intended for the propulsion of motor vehicles of categories M and N with regard to the measurement of net power and the maximum 30 minutes power of electric drive trains (OJ L 326, 24.11.2006, p. 55).

- (b) in the case of a trailer:
- the mass of the vehicle including the fuel and liquids, fitted with the standard equipment in accordance with the manufacturer's specifications, and, when they are fitted, the mass of the bodywork, additional coupling(s), the spare wheel(s) and the tools;
- (8) 'rated engine speed' (S) means the declared engine speed in min^{-1} (rpm) at which the engine develops its rated maximum net power pursuant to UNECE Regulation No 85 or, where the rated maximum net power is reached at several engine speeds, the highest one of those speeds;
- (9) 'power to mass ratio index' (PMR) means a numerical quantity calculated in accordance with the formula set out in point 4.1.2.1.1 of Annex II;
- (10) 'reference point' means one of the following points:
- (a) in the case of vehicles of categories M_1 and N_1 :
- (i) for front engine vehicles, the front end of the vehicle;
- (ii) for mid engine vehicles, the centre of the vehicle;
- (iii) for rear engine vehicles, the rear end of the vehicle.
- (b) in the case of vehicles of categories M_2 , M_3 , N_2 and N_3 , the border of the engine closest to the front of the vehicle.
- (11) 'target acceleration' means acceleration at a partial throttle condition in urban traffic as derived from statistical investigations;
- (12) 'engine' means the power source without detachable accessories;
- (13) 'reference acceleration' means the required acceleration during the acceleration test on the test track;
- (14) 'gear ratio weighting factor' (k) means a dimensionless numerical quantity used to combine the test results of two gear ratios for the acceleration test and the constant speed test;
- (15) 'partial power factor' (k_p) means a numerical quantity with no dimension used for the weighted combination of the test results of the acceleration test and the constant speed test for vehicles;
- (16) 'pre-acceleration' means the application of an acceleration control device prior to AA' for the purpose of achieving stable acceleration between AA' and BB' as referred to in Figure 1 of the Appendix to Annex II;
- (17) 'locked gear ratios' means the control of transmission such that the transmission gear cannot change during a test;
- (18) 'silencing system' means a complete set of components necessary for limiting the noise produced by an engine and its exhaust;
- (19) 'silencing system of different types' means silencing systems which significantly differ in respect of at least one of the following:
- (a) trade names or trade marks of their components;
- (b) the characteristics of the materials constituting their components, except for the coating of those components;
- (c) the shape or size of their components;
- (d) the operating principles of at least one of their components;
- (e) the assembly of their components;
- (f) the number of exhaust silencing systems or components;

- (20) 'design family of silencing system or silencing system components' means a group of silencing systems, or components thereof, in which all of the following characteristics are the same:
- (a) the presence of net gas flow of the exhaust gases through the absorbing fibrous material when in contact with that material;
 - (b) the type of the fibres;
 - (c) where applicable, binder material specifications;
 - (d) average fibre dimensions;
 - (e) minimum bulk material packing density in kg/m³;
 - (f) maximum contact surface between the gas flow and the absorbing material;
- (21) 'replacement silencing system' means any part of the silencing system, or components thereof, intended for use on a vehicle, other than a part of the type fitted to the vehicle when submitted for EU type-approval pursuant to this Regulation;
- (22) 'Acoustic Vehicle Alerting System' (AVAS) means a system for hybrid electric and pure electric vehicles which provides sound to signal the vehicle's presence to pedestrians and other road users;
- (23) 'point of sale' means a location where vehicles are stored and offered for sale to consumers;
- (24) 'technical promotional material' means technical manuals, brochures, leaflets and catalogues, whether they appear in printed, electronic or online form, as well as websites, and the purpose of which is to promote vehicles to the general public.

Article 4

General obligations of Member States

1. Subject to the dates of phases of application set out in Annex III to this Regulation and without prejudice to Article 23 of Directive 2007/46/EC, Member States shall refuse, on grounds relating to the permissible sound level, to grant EU type-approval in respect of a type of motor vehicle which does not comply with the requirements of this Regulation.

2. From 1 July 2016, Member States shall refuse, on grounds relating to the permissible sound level, to grant EU type-approval in respect of a type of replacement silencing system, or components thereof, as a separate technical unit which does not comply with the requirements of this Regulation.

Member States shall continue to grant EU type-approval, under the terms of Directive 70/157/EEC, to a replacement silencing system, or components thereof, as a separate technical unit intended for vehicles type-approved before the dates of phases of application set out in Annex III to this Regulation.

3. Subject to the dates of phases of application set out in Annex III to this Regulation, Member States shall, on grounds relating to the permissible sound level, consider certificates of conformity for new vehicles to be no longer valid for the purposes of Article 26 of Directive 2007/46/EC, and shall prohibit the registration, sale and entry into service of such vehicles where such vehicles do not comply with this Regulation.

4. Member States shall permit, on grounds relating to the permissible sound level, the sale and entry into service of a replacement silencing system, or components thereof, as a separate technical unit, if it conforms to a type in respect of which a EU type-approval has been granted in accordance with this Regulation.

Member States shall permit the sale and entry into service of replacement silencing systems, or components thereof, holding an EU type-approval as a separate technical unit under the terms of Directive 70/157/EEC intended for vehicles type-approved before the dates of phases of application set out in Annex III to this Regulation.

Article 5

General obligations of manufacturers

1. Manufacturers shall ensure that vehicles, their engine and their silencing system are designed, constructed and assembled so as to enable such vehicles, when in normal use, to comply with this Regulation, despite the vibration to which such vehicles are inherently subjected.

2. Manufacturers shall ensure that silencing systems are designed, constructed and assembled so as to be able to reasonably resist the corrosive phenomena to which they are exposed having regard to the conditions of use of vehicles, including regional climate differences.
3. The manufacturer shall be responsible to the approval authority for all aspects of the approval process and for ensuring conformity of production, whether or not the manufacturer is directly involved in all stages of the construction of a vehicle, system, component or separate technical unit.

Article 6

Additional sound emission provisions (ASEP)

1. This Article shall apply to vehicles of categories M₁ and N₁ equipped with an internal combustion engine fitted with original equipment manufacturer silencing systems, as well as to replacement silencing systems intended for such categories of vehicles in accordance with Annex IX.
2. Vehicles and replacement silencing systems shall meet the requirements of Annex VII.
3. Vehicles and replacement silencing systems shall be deemed to comply with the requirements of Annex VII, without further testing, if the manufacturer provides technical documents to the approval authority showing that the difference between the maximum and minimum engine speed of the vehicles at BB' as referred to in Figure 1 of the Appendix to Annex II, for any test condition inside the ASEP control range defined in point 2.3 of Annex VII, with respect to conditions set out in Annex II, does not exceed 0,15 x S.
4. The sound emission of the vehicle or replacement silencing system under typical on-road driving conditions, which are different from those under which the type-approval test set out in Annex II and Annex VII was carried out, shall not deviate from the test result in a significant manner.
5. The manufacturer shall not intentionally alter, adjust, or introduce any mechanical, electrical, thermal, or other device or procedure which is not operational during typical on-road driving conditions solely for the purpose of complying with the sound emission requirements under this Regulation.
6. In the application for type-approval, the manufacturer shall provide a statement, established in accordance with the model set out in the Appendix to Annex VII, that the vehicle type or replacement silencing system to be approved complies with the requirements of this Article.
7. Paragraphs 1 to 6 shall not apply to vehicles of category N₁ if one of the following conditions is met:
 - (a) the engine capacity does not exceed 660 cm³ and the power-to-mass ratio calculated by using the technically permissible maximum laden mass does not exceed 35;
 - (b) the payload is at least 850 kg and the power-to-mass ratio calculated by using the technically permissible maximum laden mass does not exceed 40.

Article 7

Consumer information and labelling

Vehicle manufacturers and distributors shall endeavour to ensure that the sound level of each vehicle in decibels (dB(a)), measured in accordance with this Regulation, is displayed in a prominent position at the point of sale and in technical promotional material.

In the light of the experience gained in the application of this Regulation, the Commission shall, by 1 July 2018 carry out a comprehensive impact assessment on labelling conditions applicable to air and noise pollution levels and on consumer information. The Commission shall report on the findings of that assessment to the European Parliament and to the Council and, if appropriate, submit a legislative proposal.

*Article 8***Acoustic Vehicle Alerting System (AVAS)**

Manufacturers shall install AVAS meeting the requirements set out in Annex VIII in new types of hybrid electric and pure electric vehicles by 1 July 2019. Manufacturers shall install AVAS in all new hybrid electric and pure electric vehicles by 1 July 2021. Before those dates, where manufacturers choose to install AVAS in vehicles, they shall ensure that those AVAS comply with the requirements set out in Annex VIII.

The Commission shall be empowered to adopt delegated acts in accordance with Article 10 in order to review Annex VIII and to include more detailed requirements on the performance of AVAS or of active safety systems, taking into account the UNECE work on that issue, by 1 July 2017.

*Article 9***Amendment of the annexes**

The Commission shall be empowered to adopt delegated acts in accordance with Article 10 to amend Annexes I, IV, VIII and X to adapt them to technical progress.

*Article 10***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in the second paragraph of Article 8 and in Article 9 shall be conferred on the Commission for a period of five years from 16 June 2014.
3. The delegation of power referred to in the second paragraph of Article 8 and in Article 9 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to the second paragraph of Article 8 or to Article 9 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 11***Revision clause**

The Commission shall carry out and publish a detailed study on sound level limits by 1 July 2021. The study shall be based on vehicles meeting the latest regulatory requirements. On the basis of the conclusions of that study, the Commission shall, where appropriate, submit a legislative proposal.

*Article 12***Amendments to Directive 2007/46/EC**

Annexes IV, VI and XI to Directive 2007/46/EC shall be amended in accordance with Annex XI to this Regulation.

*Article 13***Transitional provisions**

1. In order to check compliance of the test track as described in point 3.1.1 of Annex II, ISO 10844:1994 may be applied as an alternative to ISO 10844:2011 until 30 June 2019.
2. Vehicles with a serial hybrid drive train, which have a combustion engine with no mechanical coupling to the power train, shall be exempted from the requirements of Article 6 until 30 June 2019.

*Article 14***Repeal**

1. Without prejudice to the second subparagraph of Article 4(2) and the second subparagraph of Article 4(4), Directive 70/157/EEC is repealed with effect from 1 July 2027.
2. References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex XII to this Regulation.

*Article 15***Entry into force**

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply from 1 July 2016.
3. Point 3.1.1 of Annex II shall apply from 1 July 2019.
4. Part B of Annex XI shall apply from 1 July 2027.

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

Done at Strasbourg, 16 April 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

LIST OF ANNEXES

- Annex I EU type-approval in respect of the sound level of a vehicle type
Appendix 1: Information document
Appendix 2: Model EU type-approval certificate
- Annex II Methods and instruments for measuring the noise made by motor vehicles
Appendix: Figures
- Annex III Limit values
- Annex IV Silencing systems containing acoustically absorbing fibrous materials
Appendix: Figure 1 — Test apparatus for conditioning by pulsation
- Annex V Compressed air noise
Appendix: Figure 1 — Microphone positions for measurement of compressed air noise
- Annex VI Checks on conformity of production for vehicles
- Annex VII Measuring method to evaluate compliance with the Additional Sound Emission Provisions
Appendix: Model statement of compliance with the Additional Sound Emission Provisions
- Annex VIII Measures concerning the Acoustic Vehicle Alerting System (AVAS)
- Annex IX EU type-approval in respect of the sound level of silencing systems as separate technical units (replacement silencing systems)
Appendix 1: Information document
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Appendix 3: Model for the EU type-approval mark
Appendix 4: Test apparatus
Appendix 5: Measuring points — back pressure
- Annex X Checks on conformity of production for replacement silencing system as a separate technical unit
- Annex XI Amendments to Directive 2007/46/EC
- Annex XII Correlation table
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ANNEX I

EU TYPE-APPROVAL IN RESPECT OF THE SOUND LEVEL OF A VEHICLE TYPE

1. APPLICATION FOR EU TYPE-APPROVAL OF A VEHICLE TYPE

- 1.1. The application for EU type-approval pursuant to Article 7(1) and (2) of Directive 2007/46/EC of a vehicle type with regard to its sound level shall be submitted by the vehicle manufacturer.
- 1.2. A model for the information document is contained in Appendix 1.
- 1.3. A vehicle representative of the type in respect of which type-approval is sought shall be submitted by the vehicle manufacturer to the technical service responsible for the tests. In selecting the vehicle representative of the type, the technical service responsible for the tests shall do so to the satisfaction of the approval authority. Virtual testing methods may be used to aid decision-making during the selection process.
- 1.4. At the request of the technical service, a specimen of the silencing system and an engine of at least the same cylinder capacity and rated maximum power as that fitted to the vehicle in respect of which type-approval is sought shall also be submitted.

2. MARKINGS

- 2.1. The exhaust and intake system components, excluding fixing hardware and pipes, shall bear the following markings:
 - 2.1.1. the trade mark or name of the manufacturer of the systems and their components;
 - 2.1.2. the manufacturer's trade description.
- 2.2. The markings referred to in points 2.1.1 and 2.1.2 shall be clearly legible and indelible, even when the system is fitted to the vehicle.

3. GRANTING OF EU TYPE-APPROVAL OF A VEHICLE TYPE

- 3.1. If the relevant requirements are satisfied, EU type-approval pursuant to Article 9(3) and, if applicable, Article 10(4) of Directive 2007/46/EC shall be granted.
- 3.2. A model for the EU type-approval certificate is contained in Appendix 2.
- 3.3. An approval number in accordance with Annex VII to Directive 2007/46/EC shall be assigned to each vehicle type approved. The same Member State shall not assign the same number to another vehicle type.
 - 3.3.1. If the vehicle type complies with the limit values of Phase 1 in Annex III, Section 3 of the type-approval number shall be followed by the character 'A'. If the vehicle type complies with the limit values of Phase 2 in Annex III, Section 3 of the type-approval number shall be followed by the character 'B'. If the vehicle type complies with the limit values of Phase 3 in Annex III, Section 3 of the type-approval number shall be followed by the character 'C'.

4. AMENDMENTS TO EU TYPE-APPROVALS

In the case of amendments to the type approved pursuant to this Regulation, Articles 13, 14, 15, 16 and Article 17(4) of Directive 2007/46/EC shall apply.

5. CONFORMITY OF PRODUCTION ARRANGEMENTS

- 5.1. Measures to ensure the conformity of production arrangements shall be taken in accordance with the requirements laid down in Article 12 of Directive 2007/46/EC.
 - 5.2. Special provisions:
 - 5.2.1. The tests laid down in Annex VI to this Regulation shall correspond to those referred to in point 2.3.5 of Annex X to Directive 2007/46/EC.
 - 5.2.2. The frequency of inspections referred to in point 3 of Annex X to Directive 2007/46/EC shall normally be once every two years.
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Appendix 1

Information document No ... pursuant to Annex I of Directive 2007/46/EC relating to EU type-approval of a vehicle with respect to the permissible sound level

The following information, if applicable, shall be supplied in triplicate and include a list of contents. Any drawings shall be supplied in appropriate scale and in sufficient detail on size A4 or on a folder of A4 format. Photographs, if any, shall show sufficient detail.

If the systems, components or separate technical units have electronic controls, information concerning their performance shall be supplied.

0. GENERAL
 - 0.1. Make (trade name of manufacturer):
 - 0.2. Type:
 - 0.3. Means of identification of type, if marked on the vehicle ^(b):
 - 0.3.1. Location of that marking:
 - 0.4. Category of vehicle ^(c):
 - 0.5. Company name and address of manufacturer:
 - 0.8. Name(s) and address(es) of assembly plant(s):
 - 0.9. Name and address of the manufacturer's representative (if any):
1. GENERAL CONSTRUCTION CHARACTERISTICS OF THE VEHICLE
 - 1.1. Photographs and/or drawings of a representative vehicle:
 - 1.3. Number of axles and wheels ⁽⁴⁾:
 - 1.3.3. Powered axles (number, position, interconnection):
 - 1.6. Position and arrangement of the engine:
2. MASSES AND DIMENSIONS ⁽⁵⁾ ⁽⁶⁾ ⁽⁷⁾ (IN KG AND MM) (REFER TO DRAWING WHERE APPLICABLE)
 - 2.4. Range of vehicle dimensions (overall):
 - 2.4.1. For chassis without bodywork:
 - 2.4.1.1. Length ⁽⁸⁵⁾:
 - 2.4.1.2. Width ⁽⁸⁷⁾:
 - 2.4.2. For chassis with bodywork:
 - 2.4.2.1. Length ⁽⁸⁵⁾:
 - 2.4.2.2. Width ⁽⁸⁷⁾:
 - 2.6. Mass in running order ^(h)
 - (a) minimum and maximum for each variant:
 - (b) mass of each version (a matrix shall be provided):
 - 2.8. Technically permissible maximum laden mass stated by the manufacturer ⁽ⁱ⁾ ⁽³⁾:
3. POWER PLANT ⁽⁹⁾
 - 3.1. Manufacturer of the engine:
 - 3.1.1. Manufacturer's engine code (as marked on the engine, or other means of identification):

- 3.2. Internal combustion engine
 - 3.2.1.1. Working principle: positive ignition/compression ignition, cycle four-stroke/two-stroke/rotary ⁽¹⁾
 - 3.2.1.2. Number and arrangement of cylinders:
 - 3.2.1.2.3. Firing order:
 - 3.2.1.3. Engine capacity ^(m): ... cm³
 - 3.2.1.8. Maximum net power ⁽ⁿ⁾: ... kW at ... min⁻¹ (manufacturer's declared value)
 - 3.2.4. Fuel feed
 - 3.2.4.2. By fuel injection (compression ignition only): yes/no ⁽¹⁾
 - 3.2.4.2.2. Working principle: Direct injection/pre-chamber/swirl chamber ⁽¹⁾
 - 3.2.4.2.4. Governor
 - 3.2.4.2.4.1. Type:
 - 3.2.4.2.4.2.1. Speed at which cut-off starts under load: ... min⁻¹
 - 3.2.4.3. By fuel injection (positive ignition only): yes/no ⁽¹⁾
 - 3.2.4.3.1. Working principle: Intake manifold (single-/multi-point ⁽¹⁾)/direct injection/other (specify) ⁽¹⁾
 - 3.2.8. Intake system
 - 3.2.8.1. Pressure charger: yes/no ⁽¹⁾
 - 3.2.8.4.2. Air filter, drawings: or
 - 3.2.8.4.2.1. Make(s):
 - 3.2.8.4.2.2. Type(s):
 - 3.2.8.4.3. Intake silencer, drawings: or
 - 3.2.8.4.3.1. Make(s):
 - 3.2.8.4.3.2. Type(s):
 - 3.2.9. Silencing system
 - 3.2.9.2. Description and/or drawing of the silencing system:
 - 3.2.9.4. Exhaust silencer(s):
 - Type, marking of exhaust silencer(s):
 - Where relevant for exterior noise, reducing measures in the engine compartment and on the engine:
 - 3.2.9.5. Location of the exhaust outlet:
 - 3.2.9.6. Exhaust silencer containing fibrous materials:
 - 3.2.12.2.1. Catalytic convertor: yes/no ⁽¹⁾
 - 3.2.12.2.1.1. Number of catalytic convertors and elements (provide the information below for each separate unit):
 - 3.2.12.2.6. Particulate trap: yes/no ⁽¹⁾
- 3.3. Electric motor
 - 3.3.1. Type (winding, excitation):
 - 3.3.1.1. Maximum hourly output: ... kW
 - 3.3.1.2. Operating voltage: ... V

- 3.4. Engines or motors or combinations thereof
 - 3.4.1. Hybrid electric vehicle: yes/no ⁽¹⁾
 - 3.4.2. Category of hybrid electric vehicle: off-vehicle charging/non off-vehicle charging ⁽¹⁾
 - 3.4.3. Operating mode switch: with/without ⁽¹⁾
 - 3.4.3.1. Selectable modes
 - 3.4.3.1.1. Pure electric: yes/no ⁽¹⁾
 - 3.4.3.1.2. Pure fuel consuming: yes/no ⁽¹⁾
 - 3.4.3.1.3. Hybrid modes: yes/no ⁽¹⁾ (if yes, short description):
 - 3.4.5. Electric motor (describe each type of electric motor separately)
 - 3.4.5.1. Make:
 - 3.4.5.2. Type:
 - 3.4.5.4. Maximum power: ... kW
- 4. TRANSMISSION ^(*)
 - 4.2. Type (mechanical, hydraulic, electric, etc.):
 - 4.6. Gear ratios

Gear	Internal gearbox ratios (ratios of engine to gearbox output shaft revolutions)	Final drive ratio(s) (ratio of gearbox output shaft to driven wheel revolutions)	Total gear ratios
Maximum for CVT (*)			
1			
2			
3			
...			
Minimum for CVT (*)			
Reverse			

(*) Continuously variable transmission

- 4.7. Maximum vehicle design speed (in km/h) ⁽⁹⁾:
 - 6. SUSPENSION
 - 6.6. Tyres and wheels
 - 6.6.1. Tyre/wheel combination(s)
 - (a) for tyres indicate size designation, load-capacity index and speed category symbol,
 - (b) for wheels indicate rim size(s) and off-set(s).
 - 6.6.2. Upper and lower limits of rolling radii
 - 6.6.2.1. Axle 1:
 - 6.6.2.2. Axle 2:
 - 6.6.2.3. Axle 3:
 - 6.6.2.4. Axle 4:
- etc.

- 9. BODYWORK
- 9.1. Type of bodywork using the codes defined in Part C of Annex II to Directive 2007/46/EC:
- 9.2. Materials used and method of construction:
- 12. MISCELLANEOUS
- 12.5. Details of any non-engine devices designed to reduce noise (if not covered by other items):

Date:

Signed:

Position in company:

Appendix 2

Model EU type-approval certificate
(Maximum Format: A4 (210 × 297 mm))

Stamp of approval authority

Communication concerning the

type-approval ⁽¹⁾extension of type-approval ⁽¹⁾refusal of type-approval ⁽¹⁾withdrawal of type-approval ⁽¹⁾

of a type of a vehicle with regard to the sound level (Regulation (EU) No 540/2014).

Type-approval number:

Reason for extension:

SECTION I

0.1. Make (trade name of manufacturer):

0.2. Type:

0.3. Means of identification of type if marked on the vehicle ⁽²⁾:

0.3.1. Location of that marking:

0.4. Category of vehicle ⁽³⁾:

0.5. Company name and address of manufacturer:

0.8. Name(s) and address(es) of assembly plant(s):

0.9. Name and address of the manufacturer's representative (if any):

SECTION II

1. Additional information (where applicable): See Addendum

2. Technical service responsible for carrying out the tests:

3. Date of test report:

4. Number of test report:

5. Remarks (if any): See Addendum

6. Place:

7. Date:

8. Signature:

Attachments: Information package

Test report (for systems)/Test results (for whole vehicles)

⁽¹⁾ Delete where not applicable.⁽²⁾ If the means of identification of type contains characters not relevant to describe the vehicle types covered by the type-approval certificate such characters shall be represented in the documentation by the symbol: '?' (e.g. ABC??123??).⁽³⁾ As defined in Annex IIA to Directive 2007/46/EC.

Addendum

to EU type-approval certificate No ...

1. Additional information
 - 1.1. Power plant
 - 1.1.1. Manufacturer of the engine:
 - 1.1.2. Manufacturer's engine code:
 - 1.1.3. Maximum net power (g): ... kW at ... min⁻¹ or maximum continuous rated power (electric motor) ... kW ⁽¹⁾
 - 1.1.4. Pressure charger(s), make and type:
 - 1.1.5. Air filter, make and type:
 - 1.1.6. Intake silencer(s), make and type:
 - 1.1.7. Exhaust silencer(s), make and type:
 - 1.1.8. Catalyst(s), make and type:
 - 1.1.9. Particulate trap(s), make and type:
 - 1.2. Transmission
 - 1.2.1. Type (mechanical, hydraulic, electric, etc.):
 - 1.3. Non-engine devices designed to reduce noise:
2. Test results
 - 2.1. Sound level of moving vehicle: ... dB(A)
 - 2.2. Sound level of stationary vehicle: ... dB(A) at ... min⁻¹
 - 2.2.1. Sound level of compressed air, service brake: ... dB(A)
 - 2.2.1. Sound level of compressed air, parking brake: ... dB(A)
 - 2.2.1. Sound level of compressed air, during the pressure regulator actuation: ... dB(A)
 - 2.3. Data to facilitate in-use compliance test of hybrid electric vehicles, where an internal combustion engine cannot operate when the vehicle is stationary
 - 2.3.1. Gear (i) or position of the gear selector chosen for the test:
 - 2.3.2. Position of the operating switch during measurement $L_{wot,(i)}$ (if switch is fitted)
 - 2.3.3. Pre-acceleration length l_{pA} ... m
 - 2.3.4. Vehicle speed at the beginning of the acceleration ... km/h
 - 2.3.5. Sound pressure level $L_{wot,(i)}$... dB(A)
3. Remarks:

⁽¹⁾ Delete where not applicable.

ANNEX II

METHODS AND INSTRUMENTS FOR MEASURING THE NOISE MADE BY MOTOR VEHICLES

1. METHODS OF MEASUREMENT

- 1.1. The noise made by the vehicle type submitted for EU type-approval shall be measured by the two methods described in this Annex for the vehicle in motion and for the vehicle when stationary. In the case of a hybrid electric vehicle where an internal combustion engine cannot operate when the vehicle is stationary, the emitted noise shall only be measured in motion.

Vehicles having a technically permissible maximum laden mass exceeding 2800 kg shall be subjected to an additional measurement of the compressed air noise with the vehicle stationary in accordance with the specifications of Annex V, if the corresponding brake equipment is part of the vehicle.

- 1.2. The values measured in accordance with the tests set out in point 1.1 of this Annex shall be entered in the test report and on a form conforming to the model contained in Appendix 2 to Annex I.

2. MEASURING INSTRUMENTS

2.1. Acoustic measurements

The apparatus used for measuring the sound level shall be a precision sound-level meter or equivalent measurement system meeting the requirements of class 1 instruments (inclusive of the recommended wind-screen, if used). Those requirements are described in 'IEC 61672-1:2002: Precision sound level meters', second edition, of the International Electrotechnical Commission (IEC).

Measurements shall be carried out using the 'fast' response of the acoustic measurement instrument and the 'A' weighting curve also described in 'IEC 61672-1:2002'. When using a system that includes a periodic monitoring of the A-weighted sound pressure level, a reading shall be made at a time interval not greater than 30 ms (milliseconds).

The instruments shall be maintained and calibrated in accordance with the instructions of the instrument manufacturer.

2.2. Compliance with requirements

Compliance of the acoustic measurement instrumentation shall be verified by the existence of a valid certificate of compliance. A certificate of compliance shall be deemed to be valid if certification of compliance with the standards was conducted within the previous 12-month period for the sound calibration device and within the previous 24-month period for the instrumentation system. All compliance testing shall be conducted by a laboratory, which is authorised to perform calibrations traceable to the appropriate standards.

2.3. Calibration of the entire Acoustic Measurement System for measurement session

At the beginning and at the end of every measurement session, the entire acoustic measurement system shall be checked by means of a sound calibrator that complies with the requirements for sound calibrators of precision class 1 as set out in IEC 60942: 2003. Without any further adjustment the difference between the readings shall be less than or equal to 0,5 dB. If that value is exceeded, the results of the measurements obtained after the previous satisfactory check shall be discarded.

2.4. Instrumentation for speed measurements

The engine speed shall be measured with instrumentation having an accuracy of $\pm 2\%$ or better at the engine speeds required for the measurements being performed.

The road speed of the vehicle shall be measured with instrumentation having an accuracy of at least $\pm 0,5$ km/h, when using continuous measurement devices.

If testing uses independent measurements of speed, this instrumentation shall meet specification limits of at least $\pm 0,2$ km/h.

2.5. Meteorological instrumentation

The meteorological instrumentation used to monitor the environmental conditions during the test shall include the following devices, which meet at least the accuracies listed below:

- temperature measuring device, ± 1 °C;
- wind speed-measuring device, $\pm 1,0$ m/s;
- barometric pressure measuring device, ± 5 hPa;
- a relative humidity measuring device, ± 5 %.

3. CONDITIONS OF MEASUREMENT

3.1. Test Site and ambient conditions

3.1.1. The surface of the test track and the dimensions of the test site shall be in accordance with ISO 10844:2011. The surface of the site shall be free of powdery snow, tall grass, loose soil or cinders. There shall be no obstacle which could affect the sound field within the vicinity of the microphone and the sound source. The observer carrying out the measurements shall so position himself as not to affect the readings of the measuring instrument.

3.1.2. Measurements shall not be made under adverse weather conditions. It shall be ensured that the results are not affected by gusts of wind.

The meteorological instrumentation shall be positioned adjacent to the test area at a height of $1,2 \text{ m} \pm 0,02 \text{ m}$. The measurements shall be made when the ambient air temperature is between $+ 5$ °C and $+ 40$ °C.

The tests shall not be carried out if the wind speed, including gusts, at microphone height exceeds 5 m/s, during the noise measurement interval.

A value representative of temperature, wind speed and direction, relative humidity, and barometric pressure shall be recorded during the noise measurement interval.

Any noise peak which appears to be unrelated to the characteristics of the general sound level of the vehicle shall be ignored in taking the readings.

The background noise shall be measured for a duration of 10 seconds immediately before and after a series of vehicle tests. The measurements shall be made with the same microphones and microphone locations used during the test. The A-weighted maximum noise pressure level shall be reported.

The background noise (including any wind noise) shall be at least 10 dB below the A-weighted noise pressure level produced by the vehicle under test. If the difference between the ambient noise and the measured noise is between 10 and 15 dB(A), the appropriate correction shall be subtracted from the readings on the noise-level meter in order to calculate the test results, as in the following table:

Difference between ambient noise and noise to be measured dB(A)	10	11	12	13	14	15
Correction dB(A)	0,5	0,4	0,3	0,2	0,1	0,0

3.2. Vehicle

3.2.1. The vehicle tested shall be representative of vehicles to be put on the market and selected by the manufacturer in agreement with the technical service, to comply with the requirements of this Regulation. Measurements shall be made without any trailer, except in the case of non-separable vehicles. At the request of the manufacturer, measurements may be made on vehicles with lift axle(s) in a raised position.

Measurements shall be made on vehicles at the test mass m_t specified in accordance with the following table:

Vehicle Category	Vehicle test mass (m_t)
M_1	$m_t = m_{r0}$
N_1	$m_t = m_{r0}$
N_2, N_3	<p>$m_t = 50$ kg per kW rated engine power</p> <p>Extra loading to reach the test mass of the vehicle shall be placed above the driven rear axle(s). The extra loading is limited to 75 % of the technically permissible maximum laden mass allowed for the rear axle. The test mass shall be achieved with a tolerance of ± 5 %.</p> <p>If the centre of gravity of the extra loading cannot be aligned with the centre of the rear axle, the test mass of the vehicle shall not exceed the sum of the front axle and the rear axle load in unladen condition plus the extra loading.</p> <p>The test mass for vehicles with more than two axles shall be the same as for a two-axle vehicle.</p>
M_2, M_3	<p>$m_t = m_{r0}$ — mass of the crew member (if applicable)</p> <p>or, if the tests are carried out on an incomplete vehicle not having bodywork,</p> <p>$m_t = 50$ kg per kW rated engine power respectively in compliance with conditions above (see category N_2, N_3).</p>

3.2.2. At the applicant's request, the vehicle of a category M_2, M_3, N_2 or N_3 shall be deemed representative of its completed type if the tests are carried out on an incomplete vehicle not having bodywork. In the test of an incomplete vehicle, all relevant soundproofing materials, panels and noise reduction components and systems shall be fitted on the vehicle as designed by the manufacturer except a part of bodywork which is built at a later stage.

No new test shall be required due to the fitting of a supplement fuel tank or re-location of the original fuel tank on the condition that other parts or structures of the vehicle apparently affecting sound emissions have not been altered.

3.2.3. Tyre rolling sound emissions are laid down in Regulation (EC) No 661/2009. The tyres to be used for the test shall be representative for the vehicle and shall be selected by the vehicle manufacturer and recorded in Addendum to Appendix 2 to Annex I to this Regulation. They shall correspond to one of the tyre sizes designated for the vehicle as original equipment. The tyre is or will be commercially available on the market at the same time as the vehicle (¹). The tyres shall be inflated to the pressure recommended by the vehicle manufacturer for the test mass of the vehicle. The tyres shall have at least 1,6 mm tread depth.

3.2.4. Before the measurements are started, the engine shall be brought to its normal operating conditions.

3.2.5. If the vehicle is fitted with more than two-wheel drive, it shall be tested in the drive which is intended for normal road use.

3.2.6. If the vehicle is fitted with one or more fans having an automatic actuating mechanism, this system shall not be interfered with during the measurements.

3.2.7. If the vehicle is equipped with a silencing system containing fibrous materials, the exhaust system is to be conditioned before the test in accordance with Annex IV.

(¹) Given that the tyre contribution for overall sound emission is significant, regard must be had for existing regulatory provisions concerning tyre/road sound emissions. Traction tyres, snow tyres and special-use tyres as defined in paragraph 2 of UNECE Regulation No 117 shall be excluded during type-approval and conformity of production measurements at the request of the manufacturer in accordance with UNECE Regulation No 117 (OJ L 307, 23.11.2011, p. 3).

4. METHODS OF TESTING

4.1. Measurement of noise of vehicles in motion

4.1.1. General test conditions

Two lines, AA' and BB', parallel to line PP' and situated respectively 10 m forward and 10 m rearward of line PP' shall be marked out on the test runway.

At least four measurements shall be made on each side of the vehicle and for each gear. Preliminary measurements may be made for adjustment purposes, but shall be disregarded.

The microphone shall be located at a distance of $7,5 \text{ m} \pm 0,05 \text{ m}$ from the reference line CC' of the track and $1,2 \text{ m} \pm 0,02 \text{ m}$ above the ground.

The reference axis for free field conditions (see IEC 61672-1:2002) shall be horizontal and directed perpendicularly towards the path of the vehicle line CC'.

4.1.2. Specific test conditions for vehicles

4.1.2.1. Vehicles of category M₁, M₂ ≤ 3 500 kg, N₁

The path of the centreline of the vehicle shall follow line CC' as closely as possible throughout the entire test, from the approach to line AA' until the rear of the vehicle passes line BB'. If the vehicle is fitted with more than two-wheel drive, it shall be tested in the drive selection which is intended for normal road use.

If the vehicle is fitted with an auxiliary manual transmission or a multi-gear axle, the position used for normal urban driving shall be used. In all cases, the gear ratios for slow movements, parking or braking shall be excluded.

The test mass of the vehicle shall be that set out in the Table in point 3.2.1.

The test speed v_{test} is $50 \text{ km/h} \pm 1 \text{ km/h}$. The test speed shall be reached when the reference point is at line PP'.

4.1.2.1.1. Power to mass ratio index (PMR)

PMR is calculated using the following formula:

$\text{PMR} = (P_n/m_t) \times 1\,000$ where P_n is measured in kW and m_t is measured in kg in accordance with point 3.2.1 of this Annex.

PMR, with no dimension, is used for the calculation of acceleration.

4.1.2.1.2. Calculation of acceleration

Acceleration calculations are applicable to M₁, N₁ and M₂ ≤ 3 500 kg categories only.

All accelerations are calculated using different speeds of the vehicle on the test track. The formulae given are used for the calculation of $a_{\text{wot } i}$, $a_{\text{wot } i+1}$ and $a_{\text{wot test}}$. The speed either at AA' or PP' is defined as the vehicle speed when the reference point passes AA' (v_{AA}) or PP' (v_{PP}). The speed at BB' is defined when the rear of the vehicle passes BB' (v_{BB}). The method used for calculating the acceleration shall be indicated in the test report.

Due to the definition of the reference point for the vehicle, the length of the vehicle (l_{veh}) is considered differently in the formula below. If the reference point is in the front of the vehicle, then $l = l_{\text{veh}}$, mid: $l = 1/2 l_{\text{veh}}$ and rear: $l = 0$.

4.1.2.1.2.1 The calculation procedure for vehicles with manual transmission, automatic transmission, adaptive transmissions and continuous variable transmissions (CVTs) tested with locked gear ratios is as follows:

$$a_{\text{wot test}} = ((v_{\text{BB}}/3,6)^2 - (v_{\text{AA}}/3,6)^2)/(2*(20+l))$$

$a_{\text{wot test}}$ used in the determination of gear selection shall be the average of the four $a_{\text{wot test, i}}$ during each valid measurement run.

Pre-acceleration may be used. The point of depressing the accelerator before line AA' shall be reported in the test report.

4.1.2.1.2.2. The calculation procedure for vehicles with automatic transmissions, adaptive transmissions and CVTs tested with non-locked gear ratios is as follows:

$a_{\text{wot test}}$ used in the determination of gear selection shall be the average of the four $a_{\text{wot test, i}}$ during each valid measurement run.

Where devices or measures described in point 4.1.2.1.4.2 can be used to control transmission operation for the purpose of achieving test requirements, $a_{\text{wot test}}$ shall be calculated using the following formula:

$$a_{\text{wot test}} = ((v_{\text{BB'}/3,6})^2 - (v_{\text{AA'}/3,6})^2) / (2 * (20 + 1))$$

Pre-acceleration may be used:

Where devices or measures described in point 4.1.2.1.4.2 are not used, $a_{\text{wot test}}$ shall be calculated using the following formula:

$$a_{\text{wot test PP-BB}} = ((v_{\text{BB'}/3,6})^2 - (v_{\text{PP'}/3,6})^2) / (2 * (10 + 1))$$

$a_{\text{wot test PP-BB}}$: acceleration between point PP and BB

Pre-acceleration shall not be used.

The location of depressing the accelerator shall be where the reference point of the vehicle passes line AA'.

4.1.2.1.2.3 Target acceleration

The target acceleration a_{urban} defines the typical acceleration in urban traffic and is derived from statistical investigations. It is a function depending on the PMR of a vehicle.

The target acceleration a_{urban} shall be calculated using the following formula:

$$a_{\text{urban}} = 0,63 * \log_{10} (\text{PMR}) - 0,09$$

4.1.2.1.2.4. Reference acceleration

The reference acceleration $a_{\text{wot ref}}$ defines the required acceleration during the acceleration test on the test track. It is a function depending on the PMR of a vehicle. That function is different for specific vehicle categories.

The reference acceleration $a_{\text{wot ref}}$ shall be calculated using the following formula:

$$a_{\text{wot ref}} = 1,59 * \log_{10} (\text{PMR}) - 1,41 \text{ for } \text{PMR} \geq 25$$

$$a_{\text{wot ref}} = a_{\text{urban}} = 0,63 * \log_{10} (\text{PMR}) - 0,09 \text{ for } \text{PMR} < 25$$

4.1.2.1.3. Partial power factor k_p

The partial power factor k_p (see point 4.1.3.1) is used for the weighted combination of the test results of the acceleration test and the constant speed test for vehicles of category M_1 and N_1 .

In cases other than a single gear test, $a_{\text{wot ref}}$ shall be used instead of $a_{\text{wot test}}$ (see point 4.1.3.1).

4.1.2.1.4. Gear ratio selection

The selection of gear ratios for the test depends on their specific acceleration potential a_{wot} under full throttle condition, in accordance with the reference acceleration $a_{\text{wot ref}}$ required for the full throttle acceleration test.

Some vehicles may have different software programs or modes for the transmission (e.g. sporty, winter, adaptive). Where the vehicle has different modes leading to valid accelerations, the vehicle manufacturer shall prove to the satisfaction of the technical service, that the vehicle is tested in the mode which achieves an acceleration closest to $a_{\text{wot ref}}$.

4.1.2.1.4.1. Vehicles with manual transmissions, automatic transmissions, adaptive transmissions or CVTs tested with locked gear ratios

The following conditions for selection of gear ratios are possible:

- (a) if one specific gear ratio gives an acceleration in a tolerance band of $\pm 5\%$ of the reference acceleration $a_{\text{wot ref}}$ not exceeding $2,0 \text{ m/s}^2$, test with that gear ratio.
- (b) if none of the gear ratios give the required acceleration, then choose a gear ratio i , with an acceleration higher and a gear ratio $i + 1$, with an acceleration lower than the reference acceleration. If the acceleration value in gear ratio i does not exceed $2,0 \text{ m/s}^2$, use both gear ratios for the test. The weighting ratio in relation to the reference acceleration $a_{\text{wot ref}}$ is calculated by:

$$k = (a_{\text{wot ref}} - a_{\text{wot (i+1)}}) / (a_{\text{wot (i)}} - a_{\text{wot (i+1)}})$$

- (c) if the acceleration value of gear ratio i exceeds $2,0 \text{ m/s}^2$, the first gear ratio that gives an acceleration below $2,0 \text{ m/s}^2$ shall be used unless gear ratio $i + 1$ provides an acceleration less than a_{urban} . In this case, two gears, i and $i + 1$ shall be used, including the gear i with the acceleration exceeding $2,0 \text{ m/s}^2$. In other cases, no other gear shall be used. The achieved acceleration $a_{\text{wot test}}$ during the test shall be used for the calculation of the partial power factor k_p instead of $a_{\text{wot ref}}$.
- (d) if the vehicle has a transmission in which there is only one selection for the gear ratio, the acceleration test shall be carried out in this vehicle gear selection. The achieved acceleration is then used for the calculation of the partial power factor k_p instead of $a_{\text{wot ref}}$.
- (e) if rated engine speed is exceeded in a gear ratio before the vehicle passes BB' the next higher gear shall be used.

4.1.2.1.4.2. Vehicles with automatic transmission, adaptive transmissions and CVTs tested with non-locked gear ratios

The gear selector position for full automatic operation shall be used.

The acceleration value $a_{\text{wot test}}$ shall be calculated as defined in point 4.1.2.1.2.2.

The test may then include a gear change to a lower range and a higher acceleration. A gear change to a higher range and a lower acceleration is not allowed. A gear shifting to a gear ratio which is not used in urban traffic shall be avoided.

Therefore, it shall be permitted to establish and use electronic or mechanical devices, including alternate gear selector positions, to prevent a downshift to a gear ratio which is typically not used at the specified test condition in urban traffic.

The achieved acceleration $a_{\text{wot test}}$ shall be greater or equal to a_{urban} .

If possible, the manufacturer shall take measures to avoid an acceleration value $a_{\text{wot test}}$ greater than $2,0 \text{ m/s}^2$.

The achieved acceleration $a_{\text{wot test}}$ shall then be used for the calculation of the partial power factor k_p (see point 4.1.2.1.3) instead $a_{\text{wot ref}}$.

4.1.2.1.5. Acceleration test

The manufacturer shall define the position of the reference point in front of line AA' of fully depressing the accelerator. The accelerator shall be fully depressed (as rapidly as is practicable) when the reference point of the vehicle reaches the defined point. The accelerator shall be kept in this depressed condition until the rear of the vehicle reaches line BB'. The accelerator shall then be released as rapidly as possible. The point of fully depressing the accelerator shall be reported in the test report. The technical service shall have the possibility of pre-testing.

In the case of articulated vehicles consisting of two non-separable units regarded as a single vehicle, the semi-trailer shall be disregarded in determining when line BB' is crossed.

4.1.2.1.6. Constant speed test

The constant speed test shall be carried out with the same gear(s) specified for the acceleration test and a constant speed of 50 km/h with a tolerance of ± 1 km/h between AA' and BB'. During the constant speed test, the acceleration control shall be positioned to maintain a constant speed between AA' and BB' as specified. If the gear is locked for the acceleration test, the same gear shall be locked for the constant speed test.

The constant speed test is not required for vehicles with a PMR < 25.

4.1.2.2. Vehicles of categories $M_2 > 3\,500$ kg, M_3 , N_2 , N_3

The path of the centreline of the vehicle shall follow line CC' as closely as possible throughout the entire test, from the approach to line AA' until the rear of the vehicle passes line BB'. The test shall be conducted without a trailer or semi-trailer. If a trailer is not readily separable from the towing vehicle, the trailer shall not be taken into consideration when assessing the crossing of line BB'. If the vehicle incorporates equipment such as a concrete mixer, a compressor, etc., this equipment shall not be in operation during the test. The test mass of the vehicle shall be set out in the table set out in point 3.2.1.

Target conditions of category $M_2 > 3\,500$ kg, N_2

When the reference point passes line BB', the engine speed $n_{BB'}$ shall be between 70 % and 74 % of speed S, at which the engine develops its rated maximum power, and the vehicle speed shall be 35 km/h \pm 5 km/h. Between line AA' and line BB' a stable acceleration condition shall be ensured.

Target conditions of category M_3 , N_3 :

When the reference point passes line BB', the engine speed $n_{BB'}$ shall be between 85 % and 89 % of speed S, at which the engine develops its rated maximum power, and the vehicle speed shall be 35 km/h \pm 5 km/h. Between line AA' and line BB' a stable acceleration condition shall be ensured.

4.1.2.2.1. Gear ratio selection

4.1.2.2.1.1. Vehicles with manual transmissions

Stable acceleration conditions shall be ensured. The gear choice shall be determined by the target conditions. If the difference in speed exceeds the given tolerance, then two gears shall be tested, one above and one below the target speed.

If more than one gear fulfils the target conditions, the gear which is closest to 35 km/h shall be used. If no gear fulfils the target condition for v_{test} , two gears shall be tested, one above and one below v_{test} . The target engine speed shall be reached under all conditions.

A stable acceleration condition shall be ensured. If a stable acceleration cannot be ensured in a gear, that gear shall be disregarded.

4.1.2.2.1.2. Vehicles with automatic transmissions, adaptive transmissions and CVTs

The gear selector position for full automatic operation shall be used. The test may then include a gear change to a lower range and a higher acceleration. A gear change to a higher range and a lower acceleration shall not be permitted. A gear shifting to a gear ratio which is not used in urban traffic, at the specified test condition, shall be avoided. Therefore, it shall be permitted to establish and use electronic or mechanical devices to prevent a downshift to a gear ratio which is typically not used at the specified test condition in urban traffic.

If the vehicle includes a transmission design, which provides only a single gear selection (drive), which limits engine speed during the test, the vehicle shall be tested using only a target vehicle speed. If the vehicle uses an engine and transmission combination that does not comply with the requirements set out in point 4.1.2.2.1.1, the vehicle shall be tested using only the target vehicle speed. The target vehicle speed ($v_{BB'}$) for the test is = 35 km/h \pm 5 km/h. A gear change to a higher range and a lower acceleration is allowed after the reference point of the vehicle passes line PP'. Two tests shall be performed, one with the end speed of $v_{test} = v_{BB'} + 5$ km/h, and one with the end speed of $v_{test} = v_{BB'} - 5$ km/h. The reported sound level shall be the result of the test with the highest engine speed obtained during the test from AA' to BB'.

4.1.2.2.2. Acceleration test

When the reference point of the vehicle reaches the line AA' the accelerator control shall be fully depressed (without operating the automatic downshift to a lower range than normally used in urban driving) and held fully depressed until the rear of the vehicle passes BB', but the reference point shall be at least 5 m behind BB'. The accelerator control shall then be released.

In the case of articulated vehicles consisting of two non-separable units regarded as a single vehicle, the semi-trailer shall be disregarded in determining when line BB' is crossed.

4.1.3. Interpretation of results

The maximum A-weighted sound pressure level indicated during each passage of the vehicle between the two lines AA' and BB' shall be noted. If a noise peak obviously out of character with the general sound pressure level is observed, the measurement shall be discarded. At least four measurements for each test condition shall be made on each side of the vehicle and for each gear ratio. Left and right side may be measured simultaneously or sequentially. The first four valid consecutive measurement results, within 2 dB(A), allowing for the deletion of non valid results (see point 3.1), shall be used for the calculation of the final result for the given side of the vehicle. The results of each side shall be averaged separately. The intermediate result is the higher value of the two averages mathematically rounded to the first decimal place.

The speed measurements at AA', BB', and PP' shall be noted and used in calculations to the first significant digit after the decimal place.

The calculated acceleration $a_{\text{wot test}}$ shall be noted to the second digit after the decimal place.

4.1.3.1. Vehicles of categories M_1 , N_1 and $M_2 \leq 3\,500$ kg

The calculated values for the acceleration test and the constant speed test are given by:

$$L_{\text{wot rep}} = L_{\text{wot (i+1)}} + k * (L_{\text{wot (i)}} - L_{\text{wot (i+1)}})$$

$$L_{\text{crs rep}} = L_{\text{crs (i+1)}} + k * (L_{\text{crs (i)}} - L_{\text{crs (i+1)}})$$

$$\text{Where } k = (a_{\text{wot ref}} - a_{\text{wot (i+1)}}) / (a_{\text{wot (i)}} - a_{\text{wot (i+1)}})$$

In the case of a single gear ratio test, the values are the test result of each test.

The final result is calculated by combining $L_{\text{wot rep}}$ and $L_{\text{crs rep}}$. The equation is:

$$L_{\text{urban}} = L_{\text{wot rep}} - k_p * (L_{\text{wot rep}} - L_{\text{crs rep}})$$

The weighting factor k_p , gives the partial power factor for urban driving. In cases other than a single gear test k_p is calculated by:

$$k_p = 1 - (a_{\text{urban}} / a_{\text{wot ref}})$$

If only one gear was specified for the test k_p is given by:

$$k_p = 1 - (a_{\text{urban}} / a_{\text{wot test}})$$

In cases where $a_{\text{wot test}}$ is less than a_{urban} :

$$k_p = 0$$

4.1.3.2. Vehicles of categories $M_2 > 3\,500$ kg, M_3 , N_2 , N_3

When one gear is tested, the final result shall be equal to the intermediate result. When two gears are tested the arithmetic mean of the intermediate results shall be calculated.

4.2. Measurement of noise emitted by stationary vehicles

4.2.1. Sound level in the vicinity of vehicles

The measurement results shall be entered into the test report referred to in the Addendum to Appendix 2 to Annex I.

4.2.2. Acoustic measurements

A precision sound level meter, or equivalent measuring system, as defined in point 2.1 shall be used for the measurements

4.2.3. Test site — local conditions as referred to in Figures 2 and 3a to 3d of the Appendix.

4.2.3.1. In the vicinity of the microphone, there shall be no obstacle that could influence the acoustical field and no person shall remain between the microphone and the noise source. The meter observer shall be positioned so as not to influence the meter reading.

4.2.4. Disturbance sound and wind interference

Readings on the measuring instruments produced by ambient noise and wind shall be at least 10 dB(A) below the sound level to be measured. A suitable windscreen may be fitted to the microphone provided that account is taken of its effect on the sensitivity of the microphone (see point 2.1).

4.2.5. Measuring method

4.2.5.1. Nature and number of measurements

The maximum sound level expressed in A-weighted decibels (dB(A)) shall be measured during the operating period referred to in point 4.2.5.3.2.1.

At least three measurements shall be taken at each measuring point.

4.2.5.2. Positioning and preparation of the vehicle

The vehicle shall be located in the centre part of the test area with the gear selector in the neutral position and the clutch engaged. If the design of the vehicle does not allow this, the vehicle shall be tested in conformity with the manufacturer's prescriptions for stationary engine testing. Before each series of measurements, the engine shall be brought to its normal operating condition, as specified by the manufacturer.

If the vehicle is fitted with a fan or fans having an automatic actuating mechanism, this system shall not be interfered with during the sound level measurements.

The engine hood or compartment cover, if so fitted, shall be closed.

4.2.5.3. Measuring of noise in proximity to the exhaust as referred to in Figure 2 and Figures 3a to 3d of the Appendix.

4.2.5.3.1. Positions of the microphone

4.2.5.3.1.1. The microphone shall be located at a distance of 0,5 m \pm 0,01 m from the reference point of the exhaust pipe defined in Figure 2 and Figures 3a to 3d of the Appendix, and at an angle of 45° (\pm 5°) to the flow axis of the pipe termination. The microphone shall be at the height of the reference point, but not less than 0,2 m from the ground surface. The reference axis of the microphone shall lie in a plane parallel to the ground surface and shall be directed toward the reference point on the exhaust outlet. If two microphone positions are possible, the location farthest laterally from the vehicle longitudinal centreline shall be used. If the flow axis of the exhaust outlet pipe is at 90° to the vehicle longitudinal centreline, the microphone shall be located at the point, which is farthest from the engine.

4.2.5.3.1.2. For vehicles having an exhaust provided with outlets spaced more than 0,3 m apart, measurements shall be made for each outlet. The highest level shall be recorded.

4.2.5.3.1.3. In the case of an exhaust provided with two or more outlets spaced less than 0,3 m apart and which are connected to the same silencer, only one measurement shall be made; the microphone position is related to the outlet nearest to one extreme edge of the vehicle or, when such outlet does not exist, to the outlet which is the highest above the ground.

- 4.2.5.3.1.4. For vehicles with a vertical exhaust (e.g. commercial vehicles) the microphone shall be placed at the height of the exhaust outlet. Its axis shall be vertical and oriented upwards. It shall be placed at a distance of $0,5 \text{ m} \pm 0,01 \text{ m}$ from the exhaust pipe reference point, but never less than $0,2 \text{ m}$ from the side of the vehicle nearest to the exhaust.
- 4.2.5.3.1.5. For exhaust outlets located under the vehicle body, the microphone shall be located a minimum of $0,2 \text{ m}$ from the nearest part of the vehicle, at a point closest to, but never less than $0,5 \text{ m}$ from the exhaust pipe reference point, and at a height of $0,2 \text{ m}$ above the ground, and not in line with the exhaust flow. If it is not physically possible, the angularity requirement in point 4.2.5.3.1.1 need not be met.
- 4.2.5.3.1.6. Examples of the position of the microphone, depending on the location of the exhaust pipe, are given in Figures 3a-3d of the Appendix.

4.2.5.3.2. Operating conditions of the engine

4.2.5.3.2.1. Target engine speed

- 75 % of the engine speed S for vehicles with a rated engine speed $\leq 5\,000 \text{ min}^{-1}$
- $3\,750 \text{ min}^{-1}$ for vehicles with a rated engine speed above $5\,000 \text{ min}^{-1}$ and below $7\,500 \text{ min}^{-1}$
- 50 % of the engine speed S for vehicles with a rated engine speed $\geq 7\,500 \text{ min}^{-1}$.

If the vehicle cannot reach such engine speed, the target engine speed shall be 5 % below the maximum possible engine speed for that stationary test.

4.2.5.3.2.2. Test procedure

The engine speed shall be gradually increased from idle to the target engine speed, not exceeding a tolerance band of $\pm 3 \%$ of the target engine speed, and held constant. Then the throttle control shall be rapidly released and the engine speed shall return to idle. The sound level shall be measured during a period of operation consisting of maintaining constant engine speed of 1 second and throughout the entire deceleration period. The maximum sound level meter reading during this period of operation, mathematically rounded to the first decimal place, shall be taken as the test value.

4.2.5.3.2.3. Test validation

The measurement shall be regarded as valid if the test engine speed does not deviate from the target engine speed by more than $\pm 3 \%$ for at least 1 second.

4.2.6. Results

At least three measurements for each test position shall be made. The maximum A-weighted sound pressure level indicated during each of the three measurements shall be recorded. The first three valid consecutive measurement results, within 2 dB(A) , allowing for the deletion of non valid results (taking into account the specifications of the test site as referred to in point 3.1), shall be used for the determination of the final result for the given measurement position. The maximum sound level, for all measurement positions, and of the three measurement results, shall constitute the final result.

5. Noise from hybrid electric vehicles of categories M_1 in motion, where an internal combustion engine cannot operate when the vehicle is stationary (data reported to facilitate testing of the vehicle in use).

5.1. In order to facilitate in-use compliance testing of hybrid electric vehicles — where an internal combustion engine cannot operate when the vehicle is stationary — the following information relating to the sound-pressure level measurements carried out in accordance with point 4.1 of Annex II for the motor vehicles in motion is referred to as in-use compliance reference data:

- (a) gear (i) or, for vehicles tested with non-locked gear ratios, the position of the gear selector chosen for the test;
- (b) position of the operating switch during measurement of the sound pressure level $L_{\text{wot,(i)}}$ (if switch is fitted).
- (c) pre-acceleration length l_{pA} in m;

- (d) average vehicle speed in km/h at the beginning of the full throttle acceleration for tests in gear (i); and
 - (e) sound pressure level $L_{\text{wot},(i)}$ in dB(A) of the wide-open-throttle tests in gear (i), defined as the maximum of the two values resulting from averaging the individual measurement results at each microphone position separately.
- 5.2. The in-use compliance reference data shall be entered in the EU type-approval certificate as specified in point 2.3 of the Addendum to Appendix 2 to Annex I.
-

Appendix

Figures

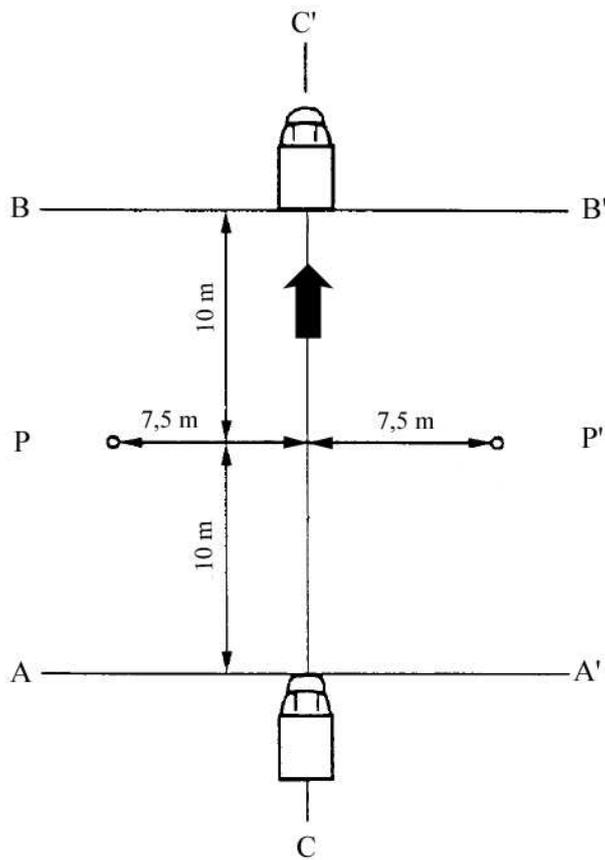
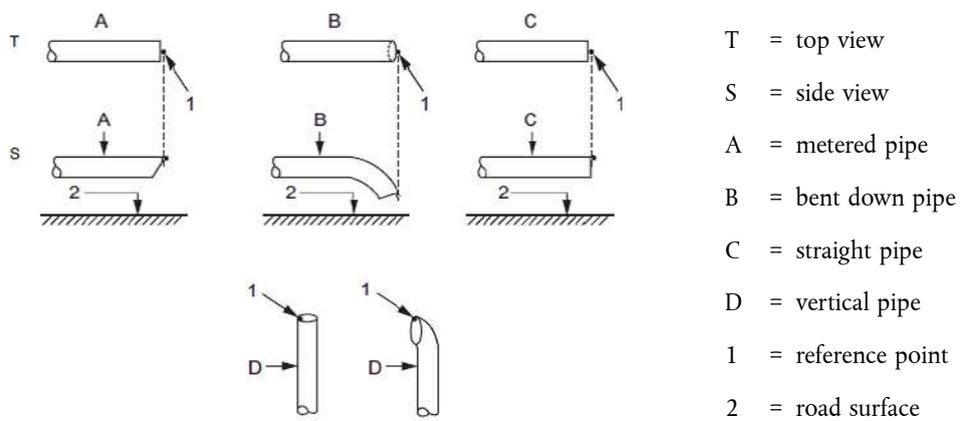


Figure 1: Measuring positions for vehicles in motion



- T = top view
- S = side view
- A = metered pipe
- B = bent down pipe
- C = straight pipe
- D = vertical pipe
- 1 = reference point
- 2 = road surface

Figure 2: Reference point

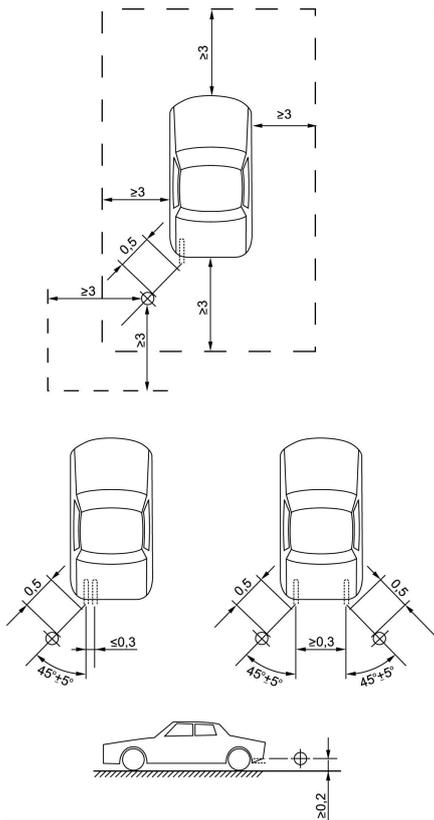


Figure 3a

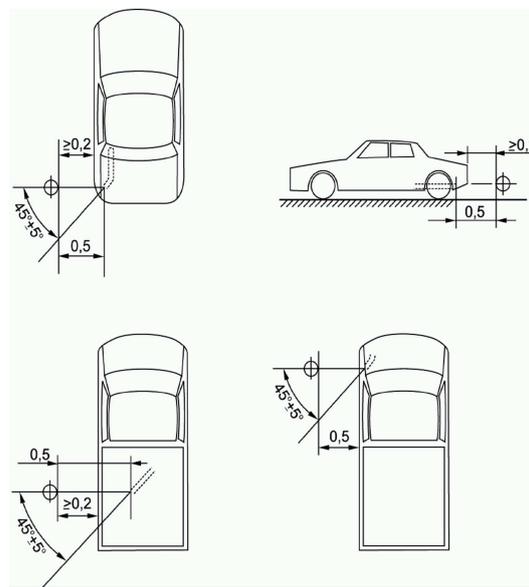


Figure 3b

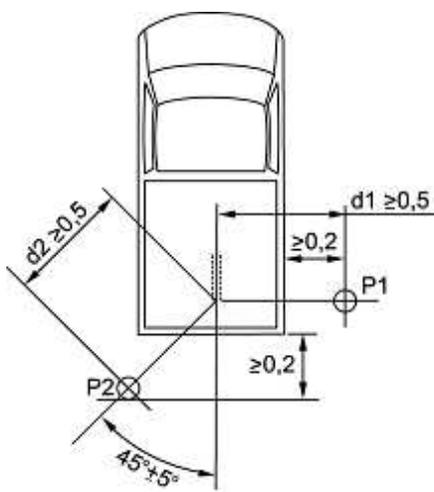


Figure 3c

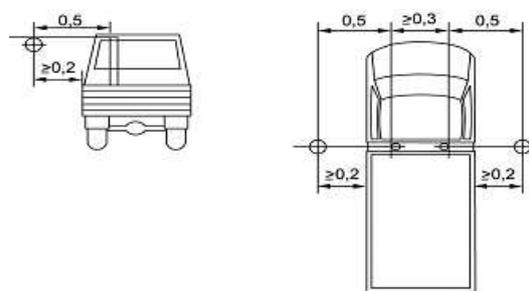


Figure 3d

Figures 3 a — d: Examples of the position of the microphone, depending on the location of the exhaust pipe

ANNEX III

LIMIT VALUES

The sound level measured in accordance with the provisions of Annex II, mathematically rounded to the nearest integer value, shall not exceed the following limits:

Vehicle category	Description of vehicle category	Limit values expressed in dB(A) [decibels (A)]		
		Phase 1 applicable for new vehicle types from 1 July 2016	Phase 2 applicable for new vehicle type from 1 July 2020 and for first registration from 1 July 2022	Phase 3 applicable for new vehicle type from 1 July 2024 and for first registration from 1 July 2026
M	Vehicles used for the carriage of passengers			
M ₁	power to mass ratio ≤ 120 kW/1 000 kg	72 ⁽¹⁾	70 ⁽¹⁾	68 ⁽¹⁾
M ₁	120 kW/1 000 kg < power to mass ratio ≤ 160 kW/1 000 kg	73	71	69
M ₁	160 kW/1 000 kg < power to mass ratio	75	73	71
M ₁	power to mass ratio > 200 kW/1 000 kg number of seats ≤ 4 R point of driver seat ≤ 450 mm from the ground	75	74	72
M ₂	mass ≤ 2 500 kg	72	70	69
M ₂	2500 kg < mass ≤ 3 500 kg	74	72	71
M ₂	3500 kg < mass ≤ 5 000 kg; rated engine power ≤ 135 kW	75	73	72
M ₂	3500 kg < mass ≤ 5 000 kg; rated engine power > 135 kW	75	74	72
M ₃	rated engine power ≤ 150 kW	76	74	73 ⁽²⁾
M ₃	150 kW < rated engine power ≤ 250 kW	78	77	76 ⁽²⁾
M ₃	rated engine power > 250 kW	80	78	77 ⁽²⁾

Vehicle category	Description of vehicle category	Limit values expressed in dB(A) [decibels (A)]		
		Phase 1 applicable for new vehicle types from 1 July 2016	Phase 2 applicable for new vehicle type from 1 July 2020 and for first registration from 1 July 2022	Phase 3 applicable for new vehicle type from 1 July 2024 and for first registration from 1 July 2026
N	Vehicles used for the carriage of goods			
N ₁	mass ≤ 2 500 kg	72	71	69
N ₁	2 500 kg < mass ≤ 3 500 kg	74	73	71
N ₂	rated engine power ≤ 135 kW	77	75 ⁽²⁾	74 ⁽²⁾
N ₂	rated engine power > 135 kW	78	76 ⁽²⁾	75 ⁽²⁾
N ₃	rated engine power ≤ 150 kW	79	77	76 ⁽²⁾
N ₃	150 kW < rated engine power ≤ 250 kW	81	79	77 ⁽²⁾
N ₃	rated engine power > 250 kW	82	81	79 ⁽²⁾

Limit values shall be increased by 1dB (2 dB(A) for N₃ and M₃ categories) for vehicles that meet the relevant definition for off-road vehicles set out in point 4 of Part A of Annex II to Directive 2007/46/EC.

For M₁ vehicles the increased limit values for off-road vehicles are only valid if the technically permissible maximum laden mass > 2 tonnes.

Limit values shall be increased by 2 db(A) for wheelchair accessible vehicles and armoured vehicles, as defined in Annex II to Directive 2007/46/EC.

⁽¹⁾ M₁ vehicles derived from N₁ vehicles:

M₁ vehicles with an R point > 850 mm from the ground and a total permissible laden mass more than 2 500 kg have to fulfil the limit values of N₁ (2 500 kg < mass ≤ 3 500 kg).

⁽²⁾ + two years for new vehicle type and + one year for new vehicles registration.

ANNEX IV

SILENCING SYSTEMS CONTAINING ACOUSTICALLY ABSORBING FIBROUS MATERIALS

1. GENERAL

Sound absorbing fibrous materials may be used in silencing systems, or components thereof, where either of the following conditions are fulfilled:

- (a) the exhaust gas is not in contact with the fibrous materials; or
- (b) the silencing system, or components thereof, are of the same design family as systems or components for which it has been proven, in the course of EU type-approval process in accordance with the requirements of this Regulation for another vehicle-type, that they are not subject to deterioration.

Where neither the condition in point (a) nor in point (b) of the first subparagraph is fulfilled, the complete silencing system, or components thereof, shall be submitted to a conventional conditioning using one of three installations and procedures described in points 1.1, 1.2 and 1.3.

For the purposes of point (b) of the first subparagraph, a group of silencing system, or components thereof, shall be considered as being of the same design family when all of the following characteristics are the same:

- (a) the presence of net gas flow of the exhaust gases through the absorbing fibrous material when in contact with that material;
- (b) the type of the fibres;
- (c) where applicable, binder material specifications;
- (d) average fibre dimensions;
- (e) minimum bulk material packing density in kg/m³;
- (f) maximum contact surface between the gas flow and the absorbing material.

1.1. Continuous road operation for 10 000 km.

1.1.1. 50 ± 20 % of this operation shall consist of urban driving and the remaining operation shall be long-distance runs at high speed; continuous road operation may be replaced by a corresponding test-track programme.

1.1.2. The two speed regimes shall be alternated at least twice.

1.1.3. The complete test programme shall include a minimum of 10 breaks of at least three hours duration in order to reproduce the effects of cooling and any condensation which may occur.

1.2. Conditioning on a test bench

1.2.1. Using standard parts and observing the vehicle manufacturer's instructions, the silencing system, or components thereof, shall be fitted to the vehicle referred to in point 1.3 of Annex I or the engine referred to in point 1.4 of Annex I. In the case of the vehicle referred to in point 1.3 of Annex I, the vehicle shall be mounted on a roller dynamometer. In the case of an engine referred to in point 1.4 of Annex I, the engine shall be coupled to a dynamometer.

1.2.2. The test shall be conducted in six six-hour periods with a break of at least 12 hours between each period in order to reproduce the effects of cooling and any condensation which may occur.

1.2.3. During each six-hour period, the engine shall be run, under the following conditions in turn:

- (a) five minutes at idling speed;
- (b) one-hour sequence under 1/4 load at 3/4 of rated maximum speed (S);
- (c) one-hour sequence under 1/2 load at 3/4 of rated maximum speed (S);
- (d) 10-minute sequence under full load at 3/4 of rated maximum speed (S);

- (e) 15-minute sequence under 1/2 load at rated maximum speed (S);
- (f) 30-minute sequence under 1/4 load at rated maximum speed (S).

Total duration of the six sequences: three hours.

Each period shall comprise two sequenced sets of those conditions in consecutive order from (a) to (f).

- 1.2.4. During the test, the silencing system, or components thereof, shall not be cooled by a forced draught simulating normal airflow around the vehicle. Nevertheless, at the request of the manufacturer, the silencing system or components thereof may be cooled in order not to exceed the temperature recorded at its inlet when the vehicle is running at maximum speed.

1.3. Conditioning by pulsation

- 1.3.1. The silencing system or components thereof shall be fitted to the vehicle referred to in point 1.3 of Annex I or the engine referred to in point 1.4 of Annex I. In the former case the vehicle shall be mounted on a roller dynamometer.

In the second case, the engine shall be mounted on a dynamometer. The test apparatus, a detailed diagram of which is shown in Figure 1 of the Appendix to this Annex shall be fitted at the outlet of the silencing system. Any other apparatus providing equivalent results shall be acceptable.

- 1.3.2. The test apparatus shall be adjusted in such a way that the exhaust-gas flow is alternatively interrupted and re-established by the quick-action valve for 2 500 cycles.
- 1.3.3. The valve shall open when the exhaust-gas back pressure, measured at least 100 mm downstream of the intake flange, reaches a value of between 0,35 and 0,40 kPa. It shall close when this pressure does not differ by more than 10 % from its stabilized value with the valve open.
- 1.3.4. The time-delay switch shall be set for the duration of gas exhaust resulting from the provisions laid down in point 1.3.3.
- 1.3.5. Engine speed shall be 75 % of the speed (S) at which the engine develops maximum power.
- 1.3.6. The power indicated by the dynamometer shall be 50 % of the full-throttle power measured at 75 % of engine speed (S).
- 1.3.7. Any drain holes shall be closed off during the test.
- 1.3.8. The entire test shall be completed within 48 hours.

If necessary, one cooling period shall be observed after each hour.

Appendix

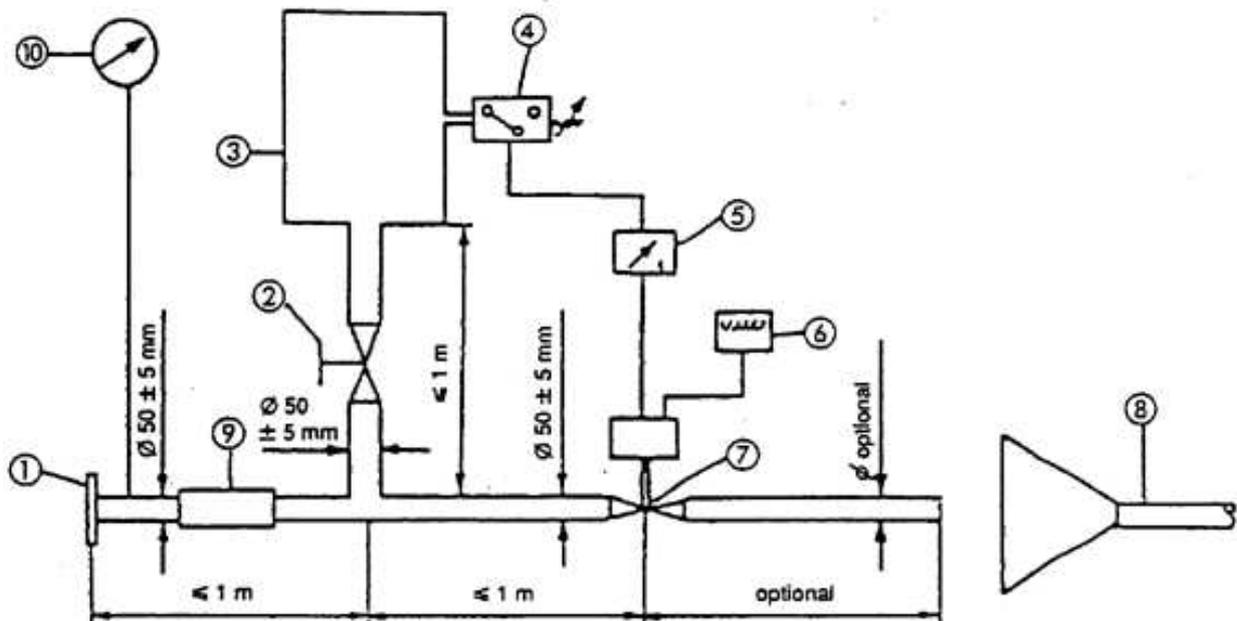


Figure 1

Test apparatus for conditioning by pulsation

1. Inlet flange or sleeve for connection to the rear of the test silencing system.
2. Hand-operated regulating valve.
3. Compensating reservoir with a maximum capacity of 40 l and a filling time of not less than one second.
4. Pressure switch with an operating range of 0,05 to 2,5 bar.
5. Time delay switch
6. Pulse counter
7. Quick-acting valve, such as exhaust brake valve 60 mm in diameter, operated by a pneumatic cylinder with an output of 120 N at 4 bar. The response time, both when opening and closing, shall not exceed 0,5 second.
8. Exhaust gas evacuation.
9. Flexible pipe.
10. Pressure gauge.

ANNEX V

COMPRESSED AIR NOISE

1. METHOD OF MEASUREMENT

The measurement is performed at microphone positions 2 and 6 as shown in Figure 1 of the Appendix, with the vehicle stationary. The highest A-weighted sound level shall be registered during venting the pressure regulator and during ventilating after the use of both the service and parking brakes.

The noise during venting the pressure regulator is measured with the engine at idling speed. The ventilating noise is registered while operating the service and parking brakes; before each measurement, the air-compressor unit has to be brought up to the highest permissible operating pressure, and then the engine switched off.

2. EVALUATION OF THE RESULTS

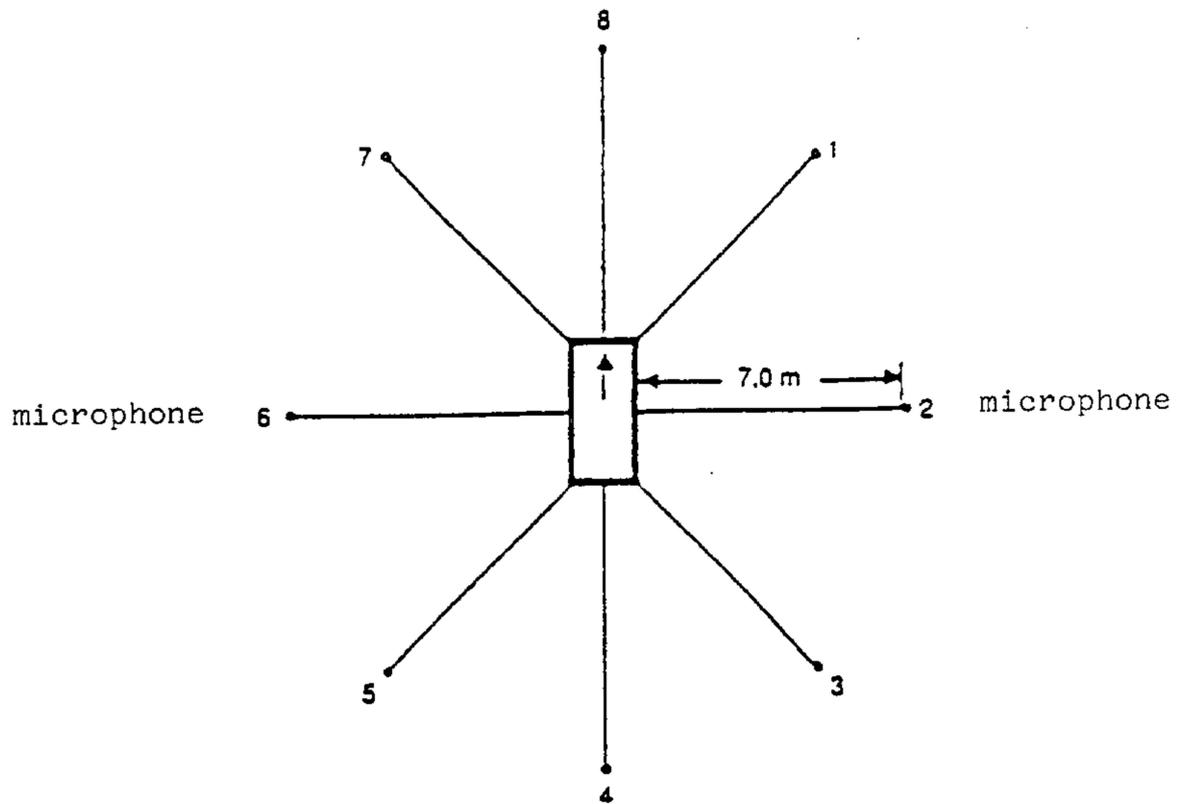
For all microphone positions two measurements are taken. In order to compensate for inaccuracies of the measuring equipment, the metre reading is reduced by 1 dB(A), and the reduced value is taken as the result of measurement. The results are taken as valid if the difference between the measurements at one microphone position does not exceed 2 dB(A). The highest value measured is taken as the result. If this value exceeds the sound level limit by 1 dB(A), two additional measurements are to be taken at the corresponding microphone position. In this case, three out of the four results of measurement obtained at this position have to comply with the sound level limit.

3. LIMITING VALUE

The sound level shall not exceed the limit of 72 dB(A).

Appendix

Figure 1: Microphone positions for measurement of compressed air noise



The measurement is performed at the stationary vehicle in accordance with Figure 1, using two microphone positions at a distance of 7 m from the contour of the vehicles and at 1,2 m above ground.

ANNEX VI

CHECKS ON CONFORMITY OF PRODUCTION FOR VEHICLES

1. GENERAL

The requirements of this Annex are consistent with the test to be held to check conformity of production (COP) in accordance with point 5 of Annex I.

2. TESTING PROCEDURE

The test site and measuring instruments shall be those described in Annex II.

2.1. The vehicle(s) under test shall be subjected to the test for measurement of sound of vehicle in motion set out in point 4.1 of Annex II.

2.2. Compressed air noise

Vehicles having a technically permissible maximum laden mass exceeding 2800 kg and equipped with compressed air systems shall be subjected to the additional test for measurement of the compressed air noise set out in point 1 of Annex V.

2.3. Additional sound emission provisions

The vehicle manufacturer shall assess the compliance with ASEP by an appropriate evaluation or may perform the test described in Annex VII.

3. SAMPLING AND EVALUATION OF THE RESULTS

One vehicle has to be chosen and subjected to the tests set out in point 2 of this Annex. If the sound level of the vehicle tested does not exceed by more than 1 dB(A) the limit value set out in Annex III, and, where appropriate, point 3 of Annex V, the vehicle type shall be considered to conform to the requirements of this Regulation.

If one of the test results does not comply with the COP requirements of Annex X to Directive 2007/46/EC, two more vehicles of the same type shall be tested pursuant to point 2 of this Annex.

If the test results for the second and the third vehicle comply with the COP requirements of Annex X to Directive 2007/46/EC, the vehicle is considered in compliance with the COP.

If one of the test results of the second or third vehicle does not comply with the COP requirements of Annex X to Directive 2007/46/EC, the vehicle type shall be considered not to conform to the requirements of this Regulation and the manufacturer shall take the necessary measures to re-establish the conformity.

ANNEX VII

MEASURING METHOD TO EVALUATE COMPLIANCE WITH THE ADDITIONAL SOUND EMISSION PROVISIONS

1. GENERAL

This Annex describes a measuring method to evaluate compliance of the vehicle with the additional sound emission provisions (ASEP) set out in Article 7.

It is not mandatory to perform actual tests when applying for EU type-approval. The manufacturer shall sign the declaration of compliance set out in the Appendix. The approval authority may ask for additional information about the declaration of compliance and carry out the tests described below.

The procedure set out in this Annex requires the performance of a test in accordance with Annex II. The test specified in Annex II shall be carried out on the same test track under conditions similar to those required in the tests prescribed in this Annex.

2. MEASURING METHOD

2.1 Measuring instruments and condition of measurements

Unless otherwise specified, the measuring instruments, the conditions of the measurements and the condition of the vehicle are equivalent to those specified in points 2 and 3 of Annex II.

If the vehicle has different modes that affect sound emission, all modes shall comply with the requirements of this Annex. In the case where the manufacturer has performed tests to prove to the approval authority compliance with those requirements, the modes used during those tests shall be reported in a test report.

2.2. Method of testing

Unless otherwise specified, the conditions and procedures of points 4.1 to 4.1.2.1.2.2 of Annex II shall be used. For the purpose of this Annex, single test runs shall be measured and evaluated.

2.3. Control range

Operation conditions are as follows:

Vehicle speed $V_{AA\ ASEP}$: $v_{AA} \geq 20$ km/h

Vehicle acceleration $a_{wot\ ASEP}$ $a_{wot} \leq 5,0$ m/s²

Engine speed $n_{BB\ ASEP}$ $n_{BB} \leq 2,0 * PMR^{-0,222} * s$ or

$n_{BB} \leq 0,9 * s$, whichever is the lowest

Vehicle speed $V_{BB\ ASEP}$:

if $n_{BB\ ASEP}$ is reached in one gear $v_{BB} \leq 70$ km/h

in all other cases $v_{BB} \leq 80$ km/h

gears $K \leq$ gear ratio i as determined in Annex II

If the vehicle, in the lowest valid gear, does not achieve the maximum engine speed below 70 km/h, the vehicle speed limit is 80 km/h.

2.4. Gear ratios

The ASEP requirements apply to every gear ratio K that leads to test results within the control range as defined in point 2.3 of this Annex.

In case of vehicles with automatic transmissions, adaptive transmissions and CVTs tested with non-locked gear ratios, the test may include a gear ratio change to a lower range and a higher acceleration. A gear change to a higher range and a lower acceleration is not allowed. A gear shift which leads to a condition that is not in compliance with the boundary conditions shall be avoided. In such a case, it is permitted to establish and use electronic or mechanical devices, including alternate gear selector positions. In order for the ASEP test to be representative and repeatable (to the approval authority), the vehicles shall be tested using production gearbox calibration.

2.5. Target conditions

The sound emission shall be measured in each valid gear ratio at the four test points as specified below.

The first test point P_1 is defined by using an entry speed v_{AA} of 20 km/h. If a stable acceleration condition cannot be achieved, the speed shall be increased in steps of 5 km/h until a stable acceleration is reached.

The fourth test point P_4 is defined by the maximum vehicle speed at BB' in that gear ratio within the boundary conditions in accordance with point 2.3.

The other two test points are calculated using the following formula:

Test Point P_j : $v_{BB_j} = v_{BB_1} + ((j - 1)/3) * (v_{BB_4} - v_{BB_1})$ for $j = 2$ and 3

Where:

v_{BB_1} = vehicle speed at BB' of test point P_1

v_{BB_4} = vehicle speed at BB' of test point P_4

Tolerance for v_{BB_j} : ± 3 km/h

For all test points the boundary conditions as specified in point 2.3 shall be met.

2.6. Test of the vehicle

The path of the centreline of the vehicle shall follow line CC' as closely as possible throughout the entire test, starting from the approach to line AA' until the rear of the vehicle passes line BB'.

At line AA' the accelerator shall be fully depressed. To achieve a more stable acceleration or to avoid a down shift between line AA' and BB' pre-acceleration before line AA' may be used. The accelerator shall be kept in depressed condition until the rear of the vehicle reaches line BB'.

For every separate test run, the following parameters shall be determined and noted:

The maximum A-weighted sound pressure level of both sides of the vehicle, indicated during each passage of the vehicle between the two lines AA' and BB', shall be mathematically rounded to the first decimal place ($L_{wot,kj}$). If a sound peak obviously out of character with the general sound pressure level is observed, the measurement shall be discarded. Left and right side may be measured simultaneously or separately.

The vehicle speed readings at AA' and BB' shall be reported with the first significant digit after the decimal place ($v_{AA,kj}$; $v_{BB,kj}$).

If applicable, the engine speed readings at AA' and BB' shall be reported as a full integer value ($n_{AA,kj}$; $n_{BB,kj}$).

The calculated acceleration shall be determined in accordance to the formula in point 4.1.2.1.2 of Annex II and reported to the second digit after the decimal place ($a_{wot,test,kj}$).

3. ANALYSIS OF RESULTS

3.1. Determination of the anchor point for each gear ratio

For measurements in gear i and lower, the anchor point consists of the maximum sound level L_{woti} , the reported engine speed n_{woti} and vehicle speed v_{woti} at BB' of gear ratio i of the acceleration test in Annex II.

$$L_{\text{anchor},i} = L_{\text{woti,Annex II}}$$

$$n_{\text{anchor},i} = n_{\text{BB,woti,Annex II}}$$

$$V_{\text{anchor},i} = V_{\text{BB,woti,Annex II}}$$

For measurements in gear $i+1$ the anchor point consists of the maximum sound level $L_{\text{woti}+1}$, the reported engine speed $n_{\text{woti}+1}$ and vehicle speed $v_{\text{woti}+1}$ at BB' of gear ratio $i+1$ of the acceleration test in Annex II.

$$L_{\text{anchor},i+1} = L_{\text{woti}+1,\text{Annex II}}$$

$$n_{\text{anchor},i+1} = n_{\text{BB,woti}+1,\text{Annex II}}$$

$$V_{\text{anchor},i+1} = V_{\text{BB,woti}+1,\text{Annex II}}$$

3.2. Slope of the regression line for each gear

The sound measurements shall be evaluated as a function of engine speed in accordance with point 3.2.1.

3.2.1. Calculation of the slope of the regression line for each gear

The linear regression line is calculated using the anchor point and the four correlated additional measurements.

$$\text{Slope}_k = \frac{\sum_{j=1}^5 (n_j - \bar{n})(L_j - \bar{L})}{\sum_{j=1}^5 (n_j - \bar{n})^2} \quad (\text{in dB/1 000 min}^{-1})$$

$$\text{With } \bar{L} = \frac{1}{5} \sum_{j=1}^5 L_j \quad \text{and} \quad \bar{n} = \bar{n} \frac{1}{5} \sum_{j=1}^5 n_j$$

where n_j = engine speed measured at line BB'

3.2.2. Slope of the regression line for each gear

The Slope_k of a particular gear for the further calculation is the derived result of the calculation in point 3.2.1 rounded to the first decimal place, but not higher than 5 dB/1 000 min⁻¹.

3.3. Calculation of the linear sound level increase expected for each measurement

The sound level $L_{\text{ASEP},kj}$ for measurement point j and gear k shall be calculated using the engine speeds measured for each measurement point, using the slope specified in point 3.2 to the specific anchor point for each gear ratio.

For $n_{\text{BB},k,j} \leq n_{\text{anchor},k}$:

$$L_{\text{ASEP},kj} = L_{\text{anchor},k} + (\text{Slope}_k - Y) * (n_{\text{BB},k,j} - n_{\text{anchor},k})/1 000$$

For $n_{\text{BB},k,j} > n_{\text{anchor},k}$:

$$L_{\text{ASEP},kj} = L_{\text{anchor},k} + (\text{Slope}_k + Y) * (n_{\text{BB},k,j} - n_{\text{anchor},k})/1 000$$

Where $Y = 1$

3.4. Samples

On request of the approval authority two additional runs within the boundary conditions in accordance with point 2.3 shall be carried out.

4. INTERPRETATION OF RESULTS

Every individual noise measurement shall be evaluated.

The sound level of every specified measurement point shall not exceed the limits given below:

$$L_{kj} \leq L_{ASEP_{k,j}} + x$$

With:

$x = 3$ dB(A) for vehicle with a non-lockable automatic transmission or non-lockable CVT

$x = 2$ dB(A) + limit value – L_{urban} of Annex II for all other vehicles

If the measured sound level at a point exceeds the limit, two additional measurements at the same point shall be carried out to verify the measurement uncertainty. The vehicle is still in compliance with ASEP, if the average of the three valid measurements at this specific point fulfils the specification.

5. REFERENCE SOUND ASSESSMENT

The reference sound is assessed at a single point in one discrete gear, simulating an acceleration condition starting with an entry speed at v_{aa} equal to 50 km/h and assuming an exit speed at v_{bb} equal to 61 km/h. The sound compliance at this point can either be calculated using the results of point 3.2.2 and the specification below or be evaluated by direct measurement using the gear as specified below.

5.1 The determination of gear K is as follows:

$K = 3$ for all manual transmission and for automatic transmission with up to 5 gears;

$K = 4$ for automatic transmission with 6 or more gears

If no discrete gears are available, e.g. for non-lockable automatic transmissions or non-lockable CVTs, the gear ratio for further calculation shall be determined from the acceleration test result in Annex II using the reported engine speed and vehicle speed at line BB'.

5.2. Determination of reference engine speed n_{ref_K}

The reference engine speed, n_{ref_K} , shall be calculated using the gear ratio of gear K at the reference speed of $v_{ref} = 61$ km/h.

5.3. Calculation of L_{ref}

$$L_{ref} = L_{anchor_K} + Slope_K * (n_{ref_K} - n_{anchor_K}) / 1\ 000$$

L_{ref} shall be less than or equal to 76 dB(A).

For vehicles fitted with a manual gear box having more than four forward gears and equipped with an engine developing a rated maximum net power greater than 140 kW and having a rated maximum net power/maximum-mass ratio greater than 75 kW/t, L_{ref} shall be less than or equal to 79 dB(A).

For vehicles fitted with an automatic gear box having more than four forward gears and equipped with an engine developing a rated maximum net power greater than 140 kW and having a rated maximum net power/maximum-mass ratio greater than 75 kW/t, L_{ref} shall be less than or equal to 78 dB(A).

6. EVALUATION OF ASEP USING THE PRINCIPLE OF L_{urban}

6.1 General

This evaluation procedure is an alternative selected by the manufacturer to the procedure described in point 3 of this Annex and is applicable to all vehicle technologies. The manufacturer shall be responsible for determining the correct manner of testing. Unless otherwise specified, all testing and calculation shall be as specified in Annex II.

6.2. Calculation of $L_{\text{urban ASEP}}$

From any $L_{\text{wot ASEP}}$ as measured in accordance with this Annex, $L_{\text{urban ASEP}}$ shall be calculated as follows:

- (a) calculate $a_{\text{wot test ASEP}}$ as specified in point 4.1.2.1.2.1 or point 4.1.2.1.2.2 of Annex II, as applicable;
- (b) determine the vehicle speed ($V_{\text{BB ASEP}}$) at BB' during the $L_{\text{wot ASEP}}$ test;
- (c) calculate $k_{\text{P ASEP}}$ as follows:

$$k_{\text{P ASEP}} = 1 - (a_{\text{urban}}/a_{\text{wot test ASEP}})$$

Test results where $a_{\text{wot test ASEP}}$ are less than a_{urban} shall be disregarded.

- (d) calculate $L_{\text{urban measured ASEP}}$ as follows:

$$L_{\text{urban measured ASEP}} =$$

$$L_{\text{wot ASEP}} - k_{\text{P ASEP}} * (L_{\text{wot ASEP}} - L_{\text{crs}})$$

For further calculation, use the L_{urban} from Annex II without rounding, including the digit after the decimal (xx.x).

- (e) calculate $L_{\text{urban normalized}}$ as follows:

$$L_{\text{urban normalized}} = L_{\text{urban measured ASEP}} - L_{\text{urban}}$$

- (f) calculate $L_{\text{urban ASEP}}$ as follows:

$$L_{\text{urban ASEP}} =$$

$$L_{\text{urban normalized}} - (0,15 * (V_{\text{BB ASEP}} - 50))$$

- (g) compliance with sound level limits:

$L_{\text{urban ASEP}}$ shall be less than or equal to 3,0 dB.

*Appendix***Model statement of compliance with the Additional Sound Emission Provisions****(Maximum format: A4 (210 × 297 mm))**

(Name of manufacturer) attests that vehicles of this type (type with regard to its sound emission pursuant to Regulation (EU) No 540/2014) comply with the requirements of Article 7 of Regulation (EU) No 540/2014.

(Name of manufacturer) makes this statement in good faith, after having performed an appropriate evaluation of the sound emission performance of the vehicles.

Date:

Name of authorized representative:

Signature of authorized representative:

ANNEX VIII

MEASURES CONCERNING THE ACOUSTIC VEHICLE ALERTING SYSTEM (AVAS)

This Annex sets out measures concerning the Acoustic Vehicle Alerting System (AVAS) for hybrid electric and pure electric vehicles.

AVAS

1. System performance

If AVAS is installed on a vehicle, it shall comply with the requirements referred to below.

2. Operation conditions

(a) Sound generation method

The AVAS shall automatically generate a sound in the minimum range of vehicle speed from start up to approximately 20 km/h and during reversing. Where the vehicle is equipped with an internal combustion engine that is in operation within the vehicle speed range defined above, the AVAS shall not generate a sound.

For vehicles having a reversing sound warning device, it is not necessary for the AVAS to generate a sound whilst reversing.

(b) Switch

The AVAS shall be fitted with a switch which is easily accessible by the vehicle driver in order to allow engaging and disengaging. Upon restarting the vehicle, AVAS shall default to the switched on position.

(c) Attenuation

The AVAS sound level may be attenuated during periods of vehicle operation.

3. Sound type and volume

(a) The sound to be generated by the AVAS shall be a continuous sound that provides information to the pedestrians and other road users of a vehicle in operation. The sound should be easily indicative of vehicle behaviour and should sound similar to the sound of a vehicle of the same category equipped with an internal combustion engine.

(b) The sound to be generated by the AVAS shall be easily indicative of vehicle behaviour, for example, through the automatic variation of sound level or characteristics in synchronization with vehicle speed.

(c) The sound level generated by the AVAS shall not exceed the approximate sound level of a vehicle of the M₁ category equipped with an internal combustion engine and operating under the same conditions.

ANNEX IX

EU TYPE-APPROVAL IN RESPECT OF THE SOUND LEVEL OF SILENCING SYSTEMS AS SEPARATE TECHNICAL UNITS (REPLACEMENT SILENCING SYSTEMS)

1. APPLICATION FOR EU TYPE-APPROVAL

- 1.1. The application of EU type-approval pursuant to Article 7(1) and (2) of Directive 2007/46/EC in respect of a replacement silencing system, or components thereof, as a separate technical unit intended for vehicles of categories M_1 and N_1 shall be submitted by the vehicle manufacturer or the manufacturer of the separate technical unit in question.
- 1.2. A model for the information document is contained in Appendix 1.
- 1.3. At the request of the technical service concerned, the applicant shall submit:
 - 1.3.1 two examples of the system in respect of which application for EU type-approval has been made,
 - 1.3.2 a silencing system of the type originally fitted to the vehicle when EU type-approval was granted,
 - 1.3.3 a vehicle representative of the type to which the system is to be fitted, which meets the requirements of point 2.1 of Annex VI,
 - 1.3.4 a separate engine corresponding to the type of vehicle described.

2. MARKINGS

- 2.4.1. The replacement silencing system, or components thereof, excluding fixing hardware and pipes shall bear:
 - 2.4.1.1. the trade mark or trade name of the manufacturer of the replacement silencing system and its components,
 - 2.4.1.2. the manufacturer's trade description.
- 2.4.2. These marks shall be clearly legible and indelible, even when the system is fitted to the vehicle.

3. GRANTING OF EU TYPE-APPROVAL

- 3.1. If the relevant requirements are satisfied, EU type-approval pursuant to Article 9(3) and, if applicable, Article 10(4) of Directive 2007/46/EC shall be granted.
- 3.2. A model for the EU type-approval certificate is contained in Appendix 2.
- 3.3. A type-approval number in accordance with Annex VII to Directive 2007/46/EC shall be assigned to each type of replacement silencing system, or components thereof, approved as a separate technical unit; section 3 of the type-approval number shall indicate the number of this Regulation. Furthermore, if the replacement silencing system is intended to be fitted on vehicle types complying with the limit values of Phase 1 in Annex III only, section 3 of the type-approval number shall be followed by the character 'A'. If the replacement silencing system is intended to be fitted on vehicle types complying with the limit values of Phase 2 in Annex III only, section 3 of the type-approval number shall be followed by the character 'B'. If the replacement silencing system is intended to be fitted on vehicle types complying with the limit values of Phase 3 in Annex III, section 3 of the type-approval number shall be followed by the character 'C'. The same Member State shall not assign the same number to another type of replacement silencing system, or components thereof.

4. EU TYPE-APPROVAL MARK

- 4.1. Every replacement silencing system, or components thereof, excluding fixing hardware and pipes, conforming to a type approved under this Regulation shall bear an EU type-approval mark.

4.2. The EU type-approval mark shall consist of a rectangle surrounding the lower case letter 'e' followed by the distinguishing letter(s) or number of the Member State which has granted the approval:

'1' for Germany

'2' for France

'3' for Italy

'4' for the Netherlands

'5' for Sweden

'6' for Belgium

'7' for Hungary

'8' for the Czech Republic

'9' for Spain

'11' for the United Kingdom

'12' for Austria

'13' for Luxembourg

'17' for Finland

'18' for Denmark

'19' for Romania

'20' for Poland

'21' for Portugal

'23' for Greece

'24' for Ireland

'25' for Croatia

'26' for Slovenia

'27' for Slovakia

'29' for Estonia

'32' for Latvia

'34' for Bulgaria

'36' for Lithuania

'49' for Cyprus

'50' for Malta

It shall also include in the vicinity of the rectangle the 'base approval number' contained in section 4 of the type-approval number referred to in Annex VII to Directive 2007/46/EC, preceded by the two figures indicating the sequence number assigned to the most recent major technical amendment to this Regulation which was applicable at the time of the vehicle type-approval. For this Regulation in its original form, the sequence number is 00. Furthermore, that sequence number shall be preceded by the character 'A' if the replacement silencing system is intended to be fitted on vehicle types complying with the limit values of Phase 1 in Annex III only, or the character 'B' if the replacement silencing system is intended to be fitted on vehicle types complying with the limit values of Phase 2 in Annex III only, or the character 'C' if the replacement silencing system is intended to be fitted on vehicle types complying with the limit values of Phase 3 in Annex III.

4.3. The mark shall be clearly legible and indelible even when the replacement silencing system, or components thereof, is fitted to the vehicle.

- 4.4. A model for the EU type-approval mark is contained in Appendix 3.
5. SPECIFICATIONS
- 5.1. General specifications
- 5.1.1. The replacement silencing system, or components thereof, shall be designed, constructed and capable of being mounted so as to ensure that the vehicle complies with this Regulation under normal conditions of use, notwithstanding any vibrations to which it may be subject.
- 5.1.2. The silencing system, or components thereof, shall be designed, constructed and capable of being mounted so that reasonable resistance to the corrosion phenomenon to which it is exposed is obtained having regard to the conditions of use of the vehicle.
- 5.1.3. Additional prescriptions related to tamperability and manually adjustable multi-mode exhaust or silencing systems
- 5.1.3.1. All exhaust or silencing systems shall be constructed in a way that does not easily permit removal of baffles, exit-cones and other parts whose primary function is as part of the silencing/expansion chambers. Where incorporation of such a part is unavoidable, its method of attachment shall be such that removal is not facilitated easily (e.g. with conventional threaded fixings) and shall also be attached such that removal causes permanent/irrecoverable damage to the assembly.
- 5.1.3.2. Exhaust or silencing systems with multiple, manually adjustable operating modes shall meet all requirements in all operating modes. The reported sound levels shall be those resulting from the mode with the highest sound levels.
- 5.2. Specifications regarding sound levels
- 5.2.1. Conditions of measurement
- 5.2.1.1. The noise test of the silencing system and the replacement silencing system has to be executed with the same normal tyres, as defined in paragraph 2 of UNECE Regulation No 117. At the request of the manufacturer, the tests shall not be done with traction tyres, special use tyres or snow tyres, as defined in paragraph 2 of UNECE Regulation No 117. Such tyres could increase the sound level of the vehicle or would have a masking effect on the noise reduction performance comparison. The tyres may be of used condition but shall satisfy legal requirements for in-traffic use.
- 5.2.2. The noise reduction performance of the replacement silencing system, or components thereof, shall be verified by means of the methods described in point 1 of Annex II. In particular, for the application of this point, reference shall be made to the amendment level of this Regulation which was in force at the time of type-approval of the new vehicle.
- (a) Measurement with running vehicle
- When the replacement silencing system, or components thereof, is mounted on the vehicle described in point 1.3.3, the sound levels obtained shall satisfy one of the following conditions:
- (i) the value measured (rounded to the nearest integer) shall not exceed by more than 1 dB(A) the type-approval value obtained under this Regulation with the type of vehicle concerned;
- (ii) the value measured (before any rounding to the nearest integer) shall not exceed by more than 1 dB(A) the noise value measured (before any rounding to the nearest integer) on the vehicle described in point 1.3.3., when this is fitted with a silencing system corresponding to the type fitted to the vehicle when submitted for type-approval under this Regulation.

Where back-to-back comparison of the replacement silencing system with the original system is chosen, for the application of point 4.1.2.1.4.2 and/or point 4.1.2.2.1.2 of Annex II, it is allowed to have a gear change to higher accelerations and the use of electronic or mechanical devices to prevent this downshift is not mandatory. If under these conditions the sound level of the test vehicle becomes higher than the COP values, the technical service will decide on the representativeness of the test vehicle.

(b) Measurement with stationary vehicle

When the replacement silencing system, or components thereof, is mounted on the vehicle described in point 1.3.3, the sound levels obtained shall satisfy one of the following conditions:

- (i) the value measured (rounded to the nearest integer) shall not exceed by more than 2 dB(A) the type-approval value obtained under this Regulation with the type of vehicle concerned;
- (ii) the value measured (before any rounding to the nearest integer) shall not exceed by more than 2 dB(A) the noise value measured (before any rounding to the nearest integer) on the vehicle described in point 1.3.3, when this is fitted with a silencing system corresponding to the type fitted to the vehicle when submitted for type-approval under this Regulation.

5.2.3. Further to the requirements of Annex II, any replacement silencing system, or components thereof, has to fulfil the applicable specifications of Annex VII. For replacement silencing systems intended for vehicles type approved in accordance with Directive 70/157/EEC the requirements of Annex VII as well as the specifications of points 5.2.3.1 to 5.2.3.3 of this Annex do not apply.

5.2.3.1. Where the replacement silencing system, or components thereof, is a system or components with variable geometry, in the application for type-approval the manufacturer shall provide a statement in conformity with the Appendix to Annex VII that the silencing system type to be approved complies with the requirements of point 5.2.3 of this Annex. The approval authority may require any relevant test to verify the compliance of the silencing system type to the additional sound emission provisions.

5.2.3.2. Where the replacement silencing system, or components thereof, is not a system with variable geometry, it is sufficient in the application for type-approval that the manufacturer provides a statement in conformity with the Appendix to Annex VII that the silencing system type to be approved complies with the requirements of point 5.2.3 of this Annex.

5.2.3.3. The compliance statement shall read as follows: '(Name of the manufacturer) attests that the silencing system of this type complies with the requirements of point 5.2.3 of Annex IX to Regulation (EU) No 540/2014. (Name of the manufacturer) makes this statement in good faith, after having performed an appropriate engineering evaluation of the sound emission performance over the applicable range of operating conditions.'

5.3. Measurement of the vehicle performances

5.3.1. The replacement silencing system, or components thereof, shall be such as to ensure that vehicle performance is comparable with that achieved with the original equipment silencing system or components thereof.

5.3.2. The replacement silencing system or, depending on the manufacturer's choice, the components of that system shall be compared with an original silencing system, or components thereof, which are also in new condition, successively mounted on the vehicle mentioned in point 1.3.3.

5.3.3. The verification shall be carried out by measuring the back pressure pursuant to point 5.3.4.

The value measured with the replacement silencing system shall not exceed the value measured with the original silencing system by more than 25 % under the conditions mentioned below.

5.3.4. Test method

5.3.4.1. Test method with engine

The measurements shall be conducted on the engine referred to in point 1.3.4 coupled to a dynamometer. With the throttle completely open, the bench shall be adjusted so as to obtain the engine speed (S) corresponding to the rated maximum power of the engine.

For the measurement of back pressure, the distance at which the pressure tap shall be placed from the exhaust manifold is indicated in Appendix 5.

5.3.4.2. Test method with vehicle

The measurements shall be carried out on the vehicle referred to point 1.3.3. The test shall be conducted either on the road or on a roller dynamometer.

With the throttle completely open, the engine shall be loaded so as to obtain the engine speed corresponding to the rated maximum power of the engine (engine speed S).

For the measurement of back pressure, the distance at which the pressure tap shall be placed from the exhaust manifold is indicated in Appendix 5.

5.4. Additional specifications regarding replacement silencing systems, or components thereof, containing acoustically absorbing fibrous materials

5.4.1. General

Sound absorbing fibrous materials may only be used in silencing systems, or components thereof, where any of the following conditions are fulfilled:

- (a) the exhaust gas is not in contact with the fibrous materials;
- (b) the silencing system, or the components thereof, are of the same design family as systems, or components thereof, for which it has been proven, in the course of the type-approval process in accordance with the requirements of this Regulation, that they are not subject to deterioration.

Unless one of those conditions is fulfilled, the complete silencing system, or components thereof, shall be submitted to conventional conditioning using one of the three installations and procedures described below.

For the purposes of point (b) of the first subparagraph, a group of silencing system or silencing system components thereof shall be considered as being of the same design family when all of the following characteristics are the same:

- (a) the presence of net gas flow of the exhaust gases through the absorbing fibrous material when in contact with that material;
- (b) the type of the fibres;
- (c) where applicable, binder material specifications;
- (d) average fibre dimensions;
- (e) minimum bulk material packing density in kg/m³;
- (f) maximum contact surface between the gas flow and the absorbing material;

5.4.1.1. Continuous road operation for 10 000 km

- 5.4.1.1.1. 50 ± 20 % of this operation shall consist of urban driving and the remaining operation shall be long-distance runs at high speed; continuous road operation may be replaced by a corresponding test-track programme.

The two speed regimes shall be alternated at least twice.

The complete test program shall include a minimum of 10 breaks of at least three-hour duration in order to reproduce the effects of cooling and any condensation which may occur.

5.4.1.2. Conditioning on a test bench

- 5.4.1.2.1. Using standard parts and observing the manufacturer's instructions, the silencing system, or components thereof, shall be fitted to the vehicle referred to in point 1.3.3 or the engine referred to in point 1.3.4. In the first case the vehicle shall be mounted on a roller dynamometer. In the second case, the engine shall be coupled to a dynamometer.

- 5.4.1.2.2. The test shall be conducted in six six-hour periods with a break of at least 12 hours between each period in order to reproduce the effects of cooling and any condensation which may occur.
- 5.4.1.2.3. During each six-hour period, the engine shall be run under the following conditions in turn:
- (a) five minutes at idling speed;
 - (b) one-hour sequence under 1/4 load at 3/4 of rated maximum speed (S);
 - (c) one-hour sequence under 1/2 load at 3/4 of rated maximum speed (S);
 - (d) 10-minute sequence under full load at 3/4 of rated maximum speed (S);
 - (e) 15-minute sequence under 1/2 load at rated maximum speed (S);
 - (f) 30-minute sequence under 1/4 load at rated maximum speed (S).

Each period shall comprise two sequenced sets of those conditions in consecutive order from (a) to (f).

- 5.4.1.2.4. During the test, the silencing system, or components thereof, shall not be cooled by a forced draught simulation normal airflow around the vehicle.

Nevertheless, at the request of the manufacturer, the silencing system, or components thereof, may be cooled in order not to exceed the temperature recorded at its inlet when the vehicle is running at maximum speed.

5.4.1.3. Conditioning by pulsation

- 5.4.1.3.1. The silencing system, or components thereof, shall be fitted to the vehicle referred to in point 1.3.3 or to the engine referred to in point 1.3.4. In the first case, the vehicle shall be mounted on a roller dynamometer, and, in the second case, the engine shall be mounted on a dynamometer.
- 5.4.1.3.2. The test apparatus, a detailed diagram of which is shown in Figure 1 of the Appendix to Annex IV shall be fitted at the outlet of the silencing system. Any other apparatus providing equivalent results is acceptable.
- 5.4.1.3.3. The test apparatus shall be adjusted in such a way that the exhaust gas flow is alternately interrupted and re-established by the quick action valve for 2 500 cycles.
- 5.4.1.3.4. The valve shall open when the exhaust gas back pressure, measured at least 100 mm downstream of the intake flange, reaches a value of between 35 and 40 k_pa. It shall close when this pressure does not differ by more than 10 % from its stabilized value with the valve opened.
- 5.4.1.3.5. The time-delay switch shall be set for the duration of gas exhaust resulting from the provisions laid down in point 5.4.1.3.4.
- 5.4.1.3.6. Engine speed shall be 75 % of the speed (S) at which the engine develops maximum power.
- 5.4.1.3.7. The power indicated by the dynamometer shall be 50 % of the full-throttle power measured at 75 % of engine speed (S).
- 5.4.1.3.8. Any drain holes shall be closed off during the test.
- 5.4.1.3.9. The entire test shall be completed within 48 hours. If necessary, one cooling period will be observed after each hour.
- 5.4.1.3.10. After conditioning, the sound level is checked pursuant to point 5.2.

6. EXTENSION OF EU TYPE-APPROVAL

The silencing system manufacturer or his representative may ask the administrative department which has granted the EU type-approval of the silencing system for one or several types of vehicles, for an extension of the approval to other types of vehicles.

The procedure is that set out in point 1. Notice of the extension of the EU type-approval (or refusal of extension) shall be communicated to the Member States in accordance with the procedure specified in Directive 2007/46/EC.

7. MODIFICATION OF THE TYPE OF SILENCING SYSTEM

In the case of modifications of the type approved pursuant to this Regulation, Articles 13 to 16 and Article 17(4) of Directive 2007/46/EC shall apply.

8. COP

8.1. Measures to ensure the conformity of production shall be taken in accordance with the requirements laid down in Article 12 of Directive 2007/46/EC.

8.2. Special provisions:

8.2.1. The tests referred to point 2.3.5 of Annex X to Directive 2007/46/EC are those prescribed in Annex XI to this Regulation.

8.2.2. The frequency of inspections referred to in point 3 of Annex X to Directive 2007/46/EC is normally once every two years.

9. INFORMATION INTENDED FOR USERS AND TECHNICAL INSPECTION

9.1. Each replacement silencing system shall be accompanied by a paper document issued by the manufacturer of the replacement silencing system or his representative. That paper document shall at least bear the following information:

- (a) EU type-approval number of the replacement silencing system (the 5th section indicating the number of the extension of the type-approval can be omitted);
 - (b) EU type-approval mark;
 - (c) make (trade name of manufacturer);
 - (d) type and commercial description and/or part number;
 - (e) company name and address of manufacturer;
 - (f) name and address of the manufacturer's representative (if any);
 - (g) data of the vehicles for which the replacement silencing system is intended:
 - (i) make,
 - (ii) type,
 - (iii) type-approval number,
 - (iv) engine code,
 - (v) maximum engine power
 - (vi) kind of transmission
 - (vii) any restriction concerning the vehicles where the system can be mounted
 - (viii) sound level for the vehicle in motion in dB(A) and stationary sound level in dB(A) at min^{-1} (if deviating to the values of the vehicle type-approval);
 - (h) mounting instructions.
- 9.2. If the paper document referred to in point 9.1 consists of more than of sheet of paper all sheets shall bear at least a reference to the EU type-approval number.
- 9.3. The information concerning point 9.1(g) and (h) may be provided on the website of the manufacturer if the website address is indicated on the paper document.
-

Appendix 1

Information document No ... relating to EU type-approval as separate technical unit of replacement silencing systems for motor vehicles (Regulation (EU) No 540/2014)

The following information, if applicable, shall be supplied in triplicate and include a list of contents. Any drawings shall be supplied in appropriate scale and in sufficient detail on size A4 or on a folder of A4 format. Photographs, if any, shall show sufficient detail.

If the systems, components or separate technical units have electronic controls, information concerning their performance shall be supplied.

0. General
 - 0.1. Make (trade name of manufacturer):
 - 0.2. Type and general commercial description(s):
 - 0.3. Means of identification of type, if marked on the separate technical unit ^(b):
 - 0.3.1. Location of that marking:
 - 0.5. Company name and address of manufacturer:
 - 0.7. In the case of components and separate technical units, location and method of affixing of the EU type-approval mark:
 - 0.8. Address(es) of assembly plant(s):
 - 0.9. Name and address of the manufacturer's representative (if any):
1. Description of the vehicle for which the device is intended (if the device is intended to be fitted to more than one vehicle type, the information requested under this point shall be supplied for each type concerned)
 - 1.1. Make (trade name of manufacturer):
 - 1.2. Type and general commercial description(s):
 - 1.3. Means of identification of type, if marked on the vehicle:
 - 1.4. Category of vehicle:
 - 1.5. EU whole-vehicle type-approval number:
 - 1.6. Power plant:
 - 1.6.1. Manufacturer of the engine:
 - 1.6.2. Manufacturer's engine code:
 - 1.6.3. Maximum net power (g): ... kW at ... min⁻¹ or maximum continuous rated power (electric motor): ... kW
 - 1.6.4. Pressure charger(s): original part or make and marking ^(l):
 - 1.6.5. Air filter: original part or make and marking ^(l):
 - 1.6.6. Intake silencer(s): original part or make and marking ^(l):

^(b) If the means of identification of type contains characters not relevant to describe the vehicle types covered by the type-approval certificate such characters shall be represented in the documentation by the symbol: '?' (e.g. ABC??123??).

^(l) Delete where not applicable.

- 1.6.7. Exhaust silencer(s): original part or make and marking ⁽¹⁾:
- 1.6.8. Catalyst: original part or make and marking ⁽¹⁾:
- 1.6.9. Particulate Trap(s): original part or make and marking ⁽¹⁾:
- 1.7. Transmission
- 1.7.1. Type (mechanical, hydraulic, electric, etc.):
- 1.8. Non-engine devices designed to reduce noise: original part or description ⁽¹⁾:
- 1.9. Sound-level values:
 moving vehicle: ... dB(A), speed stabilised before acceleration at ... km/h;
 stationary vehicle dB(A), at ... min⁻¹
- 1.10. Value of the back pressure: ... Pa
- 1.11. Any restrictions in respect of use and mounting requirements:
2. Remarks:
3. Description of the device
- 3.1. A description of the replacement silencing system indicating the relative position of each system component, together with mounting instructions
- 3.2. Detailed drawings of each component, so that they can be easily located and identified, and reference to the materials used. These drawings shall indicate the place provided for the compulsory affixing of the EU type-approval mark
- Date:
- Signed:
- Position in company:

⁽¹⁾ Delete where not applicable.

Appendix 2

MODEL

EU type-approval certificate

(Maximum Format: A4 (210 × 297 mm))

Stamp of approval authority

Communication concerning the

- type-approval ⁽¹⁾
- extension of type-approval ⁽¹⁾
- refusal of type-approval ⁽¹⁾
- withdrawal of type-approval ⁽¹⁾

of a type of a separate technical unit of silencing systems with regard to Regulation (EU) No 540/2014

Type-approval number:

Reason for extension:

SECTION I

- 0.1. Make (trade name of manufacturer):
- 0.2. Type and general commercial description(s):
- 0.3. Means of identification of type if marked on the separate technical unit ⁽²⁾:
- 0.3.1. Location of that marking:
- 0.4. Category of vehicle ⁽³⁾:
- 0.5. Company name and address of manufacturer:
- 0.7. In the case of components and separate technical units, location and method of affixing of the EU type-approval mark:
- 0.8. Address(es) of assembly plant(s):
- 0.9. Name and address of the manufacturer's representative (if any):

SECTION II

- 1. Additional information (where applicable): See Addendum
- 2. Technical service responsible for carrying out the tests:
- 3. Date of test report:
- 4. Number of test report:

⁽¹⁾ Delete where not applicable.

⁽²⁾ If the means of identification of type contains characters not relevant to describe the vehicle types covered by the type-approval certificate such characters shall be represented in the documentation by the symbol: '?' (e.g. ABC??123??).

⁽³⁾ As defined in Annex IIA to Directive 2007/46/EC.

5. Remarks (if any): See Addendum

6. Place:

7. Date:

8. Signature:

9. The index to the information package lodged with the approval authority, which may be obtained on request, is attached.

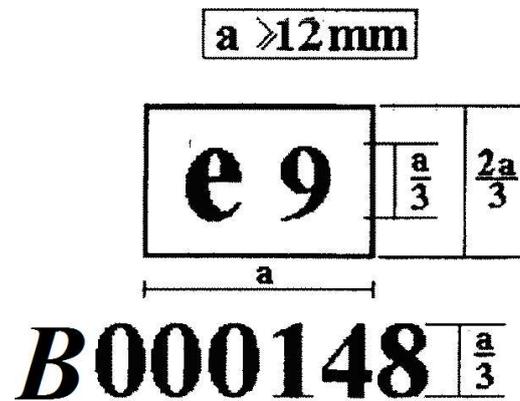
Attachments: Information package
 Test report

*Addendum***to EU type-approval certificate No ...**

1. Additional information
 - 1.1. Description of the vehicle for which the device is intended (if the device is intended to be fitted to more than one vehicle type, the information requested under this point shall be supplied for each type concerned)
 - 1.1.1. Make (trade name of manufacturer):
 - 1.1.2. Type and general commercial description(s):
 - 1.1.3. Means of identification of type, if marked on the vehicle:
 - 1.1.4. Category of vehicle:
 - 1.1.5. EU whole vehicle type-approval number:
 - 1.2. Power plant:
 - 1.2.1. Manufacturer of the engine:
 - 1.2.2. Manufacturer's engine code:
 - 1.2.3. Maximum net power (g): ... kW at ... min⁻¹ or maximum continuous rated power (electric motor) ... kW
 2. Test results
 - 2.1. Sound level of moving vehicle: ... dB(A)
 - 2.2. Sound level of stationary vehicle: ... dB(A) at ... min⁻¹
 - 2.3. Value of the back pressure: ... Pa
 3. Remarks:
-

Appendix 3

Model for the EU type-approval mark



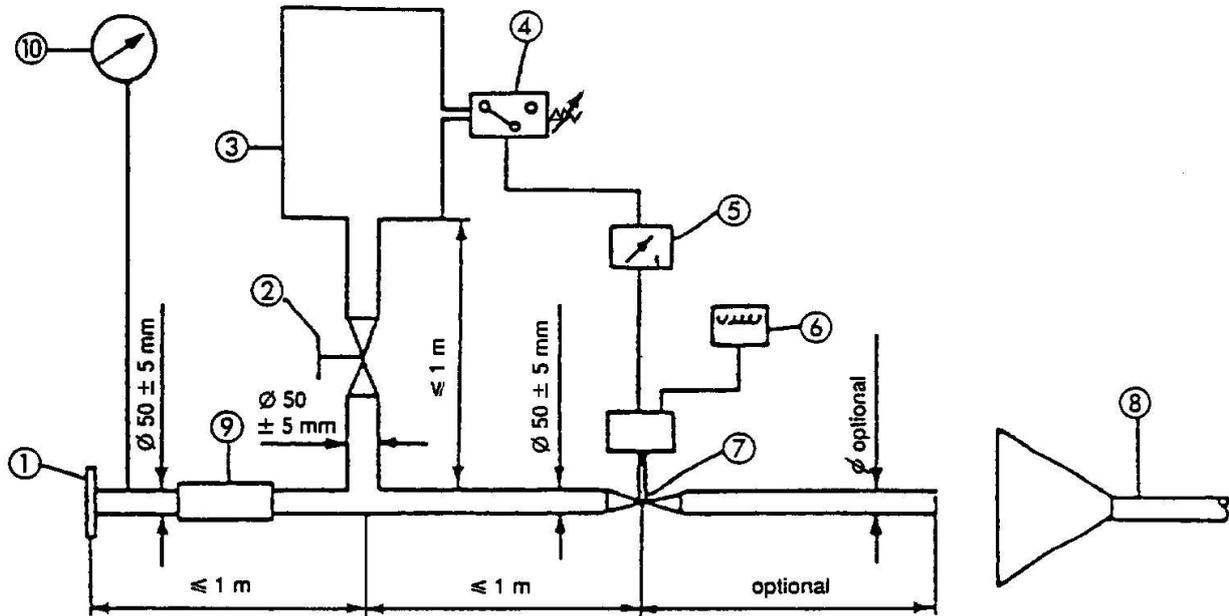
The silencing system, or components thereof, bearing the above EU type-approval mark is a device which has been approved in Spain (e 9) pursuant to Regulation (EU) No 540/2014 under the base approval number 0148, complying with the limit values of Phase 2 in Annex III to that Regulation.

The figures used are only indicative.

—

Appendix 4

Test apparatus



- 1 Inlet flange or sleeve — connection to the rear of complete silencing system to be tested.
- 2 Regulation valve (hand operated).
- 3 Compensating reservoir from 35 to 40 l.
- 4 Pressure switch 5 k_{pa} to 250 k_{pa} — to open item 7.
- 5 Time delay switch — to close item 7.
- 6 Counter of impulses.
- 7 Quick response valve — such as the valve of an exhaust brake system of 60 mm in diameter, operated by a pneumatic cylinder with an output of 120 N at 400 k_{pa}. The response time, both when opening and closing, shall not exceed 0,5 s.
- 8 Exhaust gas evacuation.
- 9 Flexible pipe.
- 10 Pressure gauge.

*Appendix 5***Measuring points — back pressure**

Examples of possible measuring points for loss-of-pressure tests. The exact measuring point shall be specified in the test report. It shall be in an area where gas flow is regular.

1. Figure 1

Single pipe

2. Figure 2

Partly twin pipe 1

¹ If not possible, refer to figure 3.

3. Figure 3

Twin pipe

² Two measuring points, one reading.

ANNEX X

CHECKS ON CONFORMITY OF PRODUCTION FOR REPLACEMENT SILENCING SYSTEM AS A SEPARATE TECHNICAL UNIT

1. GENERAL

These requirements are consistent with the test to be held to check COP in accordance with point 8 of Annex IX.

2. TESTING AND PROCEDURES

The methods of testing, measuring instruments and interpretation of results shall be those described in point 5 of Annex IX. The replacement silencing system, or components thereof, under test shall be subjected to the test as described in points 5.2, 5.3 and 5.4 of Annex IX.

3. SAMPLING AND EVALUATION OF THE RESULTS

- 3.1. One silencing system or components thereof shall be chosen and subjected to the tests of point 2. If the test results fulfil the COP requirements of point 8.1 of Annex IX, the type of silencing system or component shall be considered to be in compliance with COP.
 - 3.2. If one of the test results does not comply with the COP requirements of point 8.1 of Annex IX, two more silencing systems, or components thereof, of the same type shall be tested pursuant to point 2 of this Annex.
 - 3.3. If the test results for the second and the third silencing system, or components thereof, comply with the conformity of production requirements of point 8.1 of Annex IX, the type of silencing system, or components thereof, shall be considered to be in compliance with the conformity of production.
 - 3.4. If one of the test results for the second or third silencing system, or components thereof, does not comply with the COP requirements of point 8.1 of Annex IX, the type of silencing system, or components thereof, shall be considered not to comply with the requirements of this Regulation and the manufacturer shall take the necessary measures to re-establish the conformity.
-

ANNEX XI

AMENDMENTS TO DIRECTIVE 2007/46/EC

Directive 2007/46/EC is hereby amended as follows:

Part A

1. Annex IV shall be amended as follows:

(a) the following row shall be inserted in the table in Part I:

Item	Subject	Regulatory act	Applicability									
			M ₁	M ₂	M ₃	N ₁	N ₂	N ₃	O ₁	O ₂	O ₃	O ₄
'1A	Sound level	Regulation (EU) No 540/2014	X	X	X	X	X	X'				

(b) the following row shall be inserted in Table 1 of Appendix 1 of Part I:

Item	Subject	Regulatory act	Specific issues	Applicability and specific requirements
'1A	Sound level	Regulation (EU) No 540/2014		A'

(c) the following row shall be inserted in Table 2 of Appendix 1 of Part I:

Item	Subject	Regulatory act	Specific issues	Applicability and specific requirements
'1A	Sound level	Regulation (EU) No 540/2014		A'

2. In Annex VI, the following row shall be inserted in the table in the Appendix to Model A:

Item	Subject	Regulatory act reference	As amended by	Applicable to versions
'1A	Sound Level	Regulation (EU) No 540/2014'		

3. Annex XI shall be amended as follows:

(a) in Appendix 1, the following row shall be inserted in the table:

Item	Subject	Regulatory act reference	M ₁ ≤ 2 500 (!) kg	M ₁ > 2 500 (!) kg	M ₂	M ₃
'1A	Sound level	Regulation (EU) No 540/2014	H	G+H	G+H	G+H'

(b) in Appendix 2, the following row shall be inserted in the table:

Item	Subject	Regulatory act reference	M ₁	M ₂	M ₃	N ₁	N ₂	N ₃	O ₁	O ₂	O ₃	O ₄
'1A	Sound level	Regulation (EU) No 540/2014	X	X	X	X	X	X'				

(c) in Appendix 3, the following row shall be inserted in the table:

Item	Subject	Regulatory act reference	M ₁
'1A	Sound level	Regulation (EU) No 540/2014	X'

(d) in Appendix 4, the following row shall be inserted in the table:

Item	Subject	Regulatory act reference	M ₁	M ₂	M ₃	N ₁	N ₂	N ₃	O ₁	O ₂	O ₃	O ₄
'1A	Sound level	Regulation (EU) No 540/2014		H	H	H	H	H'				

(e) in Appendix 5, the following row shall be inserted in the table:

Item	Subject	Regulatory act reference	Mobile crane of category N 3
'1A	Sound level	Regulation (EU) No 540/2014	T'

Part B

1. Annex IV shall be amended as follows:

- (a) Item 1 in the table in Part I shall be deleted;
- (b) Item 1 in Table 1 of Appendix 1 to Part I shall be deleted;
- (c) Item 1 in Table 2 of Appendix 1 to Part I shall be deleted;
- (d) Item 1 of the table in Part II shall be deleted.

2. In Annex VI, in the table in the Appendix to Model A, Item 1 shall be deleted.

3. Annex XI shall be amended as follows:

- (a) Item 1 in the table in Appendix 1 shall be deleted;
- (b) Item 1 in the table in Appendix 2 shall be deleted;
- (c) Item 1 in the table in Appendix 3 shall be deleted;
- (d) Item 1 in the table in Appendix 4 shall be deleted;
- (e) Item 1 in the table in Appendix 5 shall be deleted.

ANNEX XII

CORRELATION TABLE

Directive 70/157/EEC	This Regulation
Article 1	—
Article 2	Article 4(1) and (2)
Article 2a	Article 4(3) and (4)
Article 3	—
Article 4	—
Article 5	—
Annex I, point 1	Annex I, point 1
Annex I, point 3	Annex I, point 2
Annex I, point 4	Annex I, point 3
Annex I, point 5	Annex I, point 4
Annex I, point 6	Annex I, point 5
Annex I, Appendix 1	Annex I, Appendix 1
Annex I, Appendix 2	Annex I, Appendix 2
Annex I, point 2	Annex III
Annex II, points 1, 2, 3 and 4	Annex IX, points 1, 2, 3 and 4
Annex II, points 5 and 6	Annex IX, points 7 and 8
Annex II, Appendix 1	Annex IX, Appendix 1
Annex II, Appendix 2	Annex IX, Appendix 2
Annex II, Appendix 3	Annex IX, Appendix 3
Annex III	—

DIRECTIVES

DIRECTIVE 2014/56/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
amending Directive 2006/43/EC on statutory audits of annual accounts and consolidated accounts
(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 50 thereof,

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Directive 2006/43/EC of the European Parliament and of the Council ⁽³⁾ lays down the conditions for the approval and registration of persons that carry out statutory audits, the rules on independence, objectivity and professional ethics applying to those persons, and the framework for their public oversight. However, it is necessary to further harmonise those rules at Union level in order to allow for greater transparency and predictability of the requirements applying to such persons and to enhance their independence and objectivity in the performance of their tasks. It is also important to increase the minimum level of convergence with respect to the auditing standards on the basis of which the statutory audits are carried out. Moreover, in order to reinforce investor protection, it is important to strengthen public oversight of statutory auditors and audit firms by enhancing the independence of Union public oversight authorities and conferring on them adequate powers, including investigative powers and the power to impose sanctions, with a view to detecting, deterring and preventing infringements of the applicable rules in the context of the provision by statutory auditors and audit firms of auditing services.
- (2) Because of the significant public relevance of public-interest entities, which arises from the scale and complexity of their business or from the nature of their business, the credibility of the audited financial statements of public-interest entities needs to be reinforced. Consequently, the special provisions for the statutory audits of public-interest entities set out in Directive 2006/43/EC have been further developed in Regulation (EU) No 537/2014 of the European Parliament and of the Council ⁽⁴⁾. The provisions on statutory audits of public-interest entities laid down in this Directive should be applicable to statutory auditors and audit firms only in so far as they carry out statutory audits of such entities.

⁽¹⁾ OJ C 191, 29.6.2012, p. 61.

⁽²⁾ Position of the European Parliament of 3 April 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

⁽³⁾ 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, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87).

⁽⁴⁾ Regulation (EU) No 537/2014 of the European Parliament and of the Council of 16 April 2014 on specific requirements regarding statutory audit of public-interest entities (see page 77 of this Official Journal).

- (3) In accordance with the Treaty on the Functioning of the European Union (TFEU), the internal market comprises an area without internal frontiers in which the free movement of goods and services and the freedom of establishment are ensured. It is necessary to enable statutory auditors and audit firms to develop their statutory audit service activities within the Union by making it possible for them to provide such services in a Member State other than that in which they were approved. Enabling statutory auditors and audit firms to provide statutory audits under their home-country professional titles in a host Member State addresses, in particular, the needs of groups of undertakings which, owing to the increasing trade flows resulting from the internal market, draw up financial statements in several Member States and are required to have them audited under Union law. The elimination of barriers to the development of statutory audit services between Member States would contribute to the integration of the Union audit market.
- (4) Statutory audit requires adequate knowledge of matters such as company law, fiscal law and social law which may vary from one Member State to another. Consequently, in order to ensure the quality of the statutory audit services provided on its territory, it should be possible for a Member State to impose a compensation measure where a statutory auditor approved in another Member State wishes to be approved also on the territory of that Member State in order to set up a permanent establishment there. Such measure should take account of the professional experience of the statutory auditor concerned. It should not lead to the imposition of a disproportionate burden on the statutory auditor nor hinder or render less attractive the provision of statutory audit services in the Member State imposing the compensation measure. Member States should be allowed to approve applicant statutory auditors on the basis either of an aptitude test or of an adaptation period such as that defined in Directive 2005/36/EC of the European Parliament and of the Council ⁽¹⁾. At the end of the adaptation period, the statutory auditor should be able to integrate into the profession in the host Member State after the assessment that he possesses professional experience in that Member State.
- (5) Whilst the primary responsibility for delivering financial information should rest with the management of the audited entities, statutory auditors and audit firms play a role by actively challenging the management from a user's perspective. In order to improve audit quality, it is therefore important that the professional scepticism exercised by statutory auditors and audit firms vis-à-vis the audited entity be reinforced. Statutory auditors and audit firms should recognise the possibility that a material misstatement due to fraud or error could exist, notwithstanding the auditor's past experience of the honesty and integrity of the audited entity's management.
- (6) It is particularly relevant to reinforce independence as an essential element when carrying out statutory audits. In order to enhance the independence of statutory auditors and audit firms from the audited entity when they are carrying out statutory audits, a statutory auditor or an audit firm, and any natural person in a position to directly or indirectly influence the outcome of the statutory audit, should be independent of the audited entity and should not be involved in the audited entity's decision-making process. In order to maintain that independence, it is also important that they keep records of all threats to their independence and of the safeguards applied to mitigate those threats. Moreover, where the threats to their independence, even after the application of safeguards to mitigate those threats, are too significant, they should resign or abstain from the audit engagement.
- (7) Statutory auditors and audit firms should be independent when carrying out statutory audits of audited entities, and conflicts of interest should be avoided. In order for the independence of statutory auditors and audit firms to be determined, the concept of a network in which statutory auditors and audit firms operate has to be taken into account. The independence requirement should at least be fulfilled during the period covered by the audit report, including both the period covered by the financial statements to be audited and the period during which the statutory audit is carried out.
- (8) Statutory auditors, audit firms and their employees should in particular refrain from carrying out the statutory audit of an entity if they have a business interest or financial interest in it, and from trading in financial instruments issued, guaranteed or otherwise supported by an audited entity, other than holdings in diversified collective investment schemes. The statutory auditor or the audit firm should abstain from participating in the internal decision-making processes of the audited entity. Statutory auditors, audit firms and their employees directly involved in the statutory audit engagement should be prevented from taking up duties in the audited entity at managerial or board level until an appropriate period has elapsed since the end of the audit engagement.

⁽¹⁾ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

- (9) It is important that statutory auditors and audit firms respect the rights to private life and data protection of their clients. They should therefore be bound by strict rules on confidentiality and professional secrecy which should not, however, impede the proper enforcement of this Directive and of Regulation (EU) No 537/2014 or cooperation with the group auditor during the performance of the audit of consolidated financial statements when the parent undertaking is in a third country, provided that Directive 95/46/EC of the European Parliament and of the Council ⁽¹⁾ is complied with. However, such rules should not allow a statutory auditor or an audit firm to cooperate with third-country authorities outside the cooperation channels provided for in Chapter XI of Directive 2006/43/EC. Those confidentiality rules should also apply to any statutory auditor or audit firm that has ceased to be involved in a specific audit task.
- (10) Adequate internal organisation of statutory auditors and audit firms should help to prevent any threats to their independence. Thus, owners or shareholders of an audit firm, as well as those managing it, should not intervene in the carrying-out of a statutory audit in any way which jeopardises the independence and objectivity of the statutory auditor who carries out the statutory audit on behalf of the audit firm. Additionally, statutory auditors and audit firms should establish appropriate internal policies and procedures in relation to employees and other persons involved in the statutory audit activity within their organisations, in order to ensure compliance with their statutory obligations. Those policies and procedures should in particular seek to prevent and address any threats to independence and should ensure the quality, integrity and thoroughness of the statutory audit. Those policies and procedures should be proportionate, in view of the scale and complexity of the business of the statutory auditor or the audit firm.
- (11) The statutory audit results in the expression of an opinion that the financial statements give a true and fair view of the audited entities in accordance with the relevant financial reporting framework. Stakeholders, however, might be unaware of the limitations of an audit, as regards, for example, materiality, sampling techniques, the role of the auditor in the detection of fraud and the responsibility of managers, which can lead to an expectation gap. In order to reduce that gap, it is important to provide greater clarity as to the scope of the statutory audit.
- (12) It is important to ensure high-quality statutory audits within the Union. All statutory audits should therefore be carried out on the basis of the international auditing standards adopted by the Commission. As international auditing standards are designed to be usable for entities of all sizes, of all types and in all jurisdictions, the competent authorities in Member States should take into account the scale and complexity of the business of small undertakings when assessing the scope of application of international auditing standards. Any provision or measure adopted by a Member State in this regard should not result in statutory auditors or audit firms being unable to carry out statutory audits in compliance with the international auditing standards. Member States should be allowed to impose additional national audit procedures or requirements only if they stem from specific national legal requirements relating to the scope of the statutory audit of annual or consolidated financial statements, meaning that those requirements have not been covered by the adopted international auditing standards, or if they add to the credibility and quality of annual financial statements and consolidated financial statements. The Commission should continue to be involved in the monitoring of the content of the international auditing standards and the process for their adoption by the International Federation of Accountants (IFAC).
- (13) In the case of consolidated financial statements, it is important that there be a clear definition of the responsibilities of statutory auditors who audit different entities within the group concerned. For this purpose, the group auditor should bear full responsibility for the audit report.
- (14) In order to enhance the credibility and transparency of the quality assurance reviews performed in the Union, Member States' quality assurance systems should be governed by the competent authorities designated by the Member States to ensure public oversight of statutory auditors and audit firms. Quality assurance reviews are designed to prevent or address potential deficiencies in the manner in which statutory audits are carried out. In order to ensure that the quality assurance reviews are sufficiently comprehensive, the competent authorities, when carrying out such reviews, should take into account the scale and complexity of the activity of the statutory auditors and the audit firms.

⁽¹⁾ 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 (OJ L 281, 23.11.1995, p. 31).

- (15) In order to improve compliance with the requirements of this Directive and of Regulation (EU) No 537/2014, and in the light of the Commission Communication of 8 December 2010 entitled 'Reinforcing sanctioning regimes in the financial services sector', the power to adopt supervisory measures by, and the sanctioning powers of, competent authorities should be enhanced. Provision should be made for the imposition of administrative pecuniary sanctions on statutory auditors, audit firms and public-interest entities for identified infringements of the rules. The competent authorities should be transparent about the sanctions and measures that they apply. The adoption and publication of sanctions should respect fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, in particular the right to respect for private and family life, the right to the protection of personal data, and the right to an effective remedy and to a fair trial.
- (16) Competent authorities should be able to impose administrative pecuniary sanctions that have a real deterrent effect, for instance in an amount of up to one million euros or higher in the case of natural persons and up to a percentage of total annual turnover in the preceding financial year in the case of legal persons or other entities. That goal is better achieved by relating the pecuniary sanction to the financial situation of the person committing the breach. Without prejudice to the possibility of withdrawing the approval of the statutory auditor or audit firm concerned, other types of sanctions which have a suitable deterrent effect should be envisaged. In any case, Member States should apply identical criteria when determining the sanction to be imposed.
- (17) Whistleblowers can bring new information to the attention of competent authorities which may assist them in detecting and imposing sanctions for irregularities, including fraud. However, whistleblowers may be deterred from doing so for fear of retaliation, or may lack incentives to do so. Member States should therefore ensure that adequate arrangements are in place to encourage whistleblowers to alert them to possible infringements of this Directive or of Regulation (EU) No 537/2014 and to protect them from retaliation. Member States should also be able to provide them with incentives for doing so; however, whistleblowers should only be eligible for such incentives where they bring to light new information which they are not already legally obliged to notify and where that information results in a sanction for an infringement of this Directive or of Regulation (EU) No 537/2014. However, Member States should also ensure that whistleblowing schemes implemented by them include mechanisms that provide appropriate protection for the reported persons, particularly as regards the right to the protection of their personal data and procedures to ensure their right of defence and their right to be heard before the adoption of a decision concerning them, as well as the right to seek an effective remedy before a tribunal against such a decision. The mechanisms established should also provide appropriate protection for whistleblowers, not only as regards the right to the protection of personal data but also by ensuring that they are not victims of undue retaliation.
- (18) The public oversight of statutory auditors and audit firms encompasses the approval and registration of statutory auditors and audit firms, the adoption of standards in respect of professional ethics and internal quality control of audit firms, continuing education, and the systems of quality assurance, investigation and sanctions for statutory auditors and audit firms. In order to enhance the transparency of auditor oversight and to allow for greater accountability, each Member State should designate a single authority to be in charge of public oversight of statutory auditors and audit firms. The independence of such public oversight authorities from the audit profession is a core prerequisite for the integrity, efficiency and orderly functioning of public oversight of statutory auditors and audit firms. Consequently, the public oversight authorities should be governed by non-practitioners and Member States should establish independent and transparent procedures for the selection of such non-practitioners.
- (19) Member States should be able to create exemptions to the requirements imposed on auditing services when they are provided to cooperatives and savings banks.
- (20) Member States should be able to delegate or allow competent authorities to delegate the tasks of those competent authorities to other authorities or to bodies authorised or designated by law. Such delegation should be subject to several conditions and the competent authority concerned should bear the ultimate responsibility for the oversight.

- (21) Public oversight authorities should be vested with sufficient powers to fulfil their tasks in an effective manner. In addition, they should be provided with sufficient human and financial resources to perform their tasks.
- (22) Adequate oversight of statutory auditors and audit firms that engage in cross-border activities or are part of networks necessitates exchange of information between the public oversight authorities of the Member States. In order to protect the confidentiality of the information that may be thus exchanged, Member States should subject to the obligation of professional secrecy not only the employees of the public oversight authorities but also all persons to whom the public oversight authorities may have delegated tasks.
- (23) Where there are proper grounds for acting, shareholders, other bodies of the audited entities when defined by national law or the competent authorities responsible for the oversight of statutory auditors and audit firms or, when provided for by national law, the competent authorities responsible for the supervision of the public-interest entity should be empowered to bring a claim before a national court for the dismissal of the statutory auditor.
- (24) Audit committees, or bodies performing an equivalent function within the audited public-interest entity, have a decisive role to play in contributing to high-quality statutory audit. It is particularly important to reinforce the independence and technical competence of the audit committee by requiring that a majority of its members be independent and that at least one of its members have competence in auditing and/or accounting. The Commission Recommendation of 15 February 2005 on the role of non-executive or supervisory directors of listed companies and on the committees of the (supervisory) board ⁽¹⁾ sets out the way in which audit committees should be established and the manner in which they should function. However, in view of the size of boards in companies with reduced market capitalisation and in small and medium-sized public-interest entities, it is appropriate to provide that the functions assigned to the audit committee for such entities, or to a body performing equivalent functions within the audited entity, may be performed by the administrative or supervisory body as a whole. Public-interest entities which are undertakings for collective investment in transferable securities (UCITS) or alternative investment funds should also be exempted from the obligation to have an audit committee. This exemption takes into account the fact that, where those funds function merely for the purpose of pooling assets, the employment of an audit committee is not appropriate. UCITS and alternative investments funds, as well as their management companies, operate in a strictly defined regulatory environment and are subject to specific governance mechanisms, such as controls exercised by their depositary.
- (25) The ‘Small Business Act’ adopted by the Commission Communication of 25 June 2008 entitled “‘Think Small First’- A ‘Small Business Act’ for Europe’ and revised by the Commission Communication of 23 February 2011 entitled ‘Review of the “Small Business Act” for Europe’, recognises the central role played by small and medium-sized enterprises in the Union’s economy and aims at improving the overall approach to entrepreneurship and anchoring the ‘Think Small First’ principle in policy-making. The Europe 2020 Strategy adopted in March 2010 also calls for an improvement of the business environment, especially for small and medium-sized enterprises, including through reducing the transaction costs of doing business in the Union. Article 34 of Directive 2013/34/EU of the European Parliament and of the Council ⁽²⁾ does not require small undertakings to have their financial statements audited.
- (26) In order to preserve the rights of the parties concerned when the competent authorities of Member States cooperate with the competent authorities of third countries on the exchange of audit working papers or other relevant documents for the assessment of the quality of the audit performed, Member States should ensure that the working arrangements entered into by their competent authorities on the basis of which any such exchange takes place include sufficient safeguards to protect the business secrecy and commercial interests, including the industrial and intellectual property rights, of the audited entities. Member States should ensure that those arrangements comply and are compatible with the provisions of Directive 95/46/EC.

⁽¹⁾ OJ L 52, 25.2.2005, p. 51.

⁽²⁾ Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013 on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings, amending Directive 2006/43/EC of the European Parliament and of the Council and repealing Council Directives 78/660/EEC and 83/349/EEC (OJ L 182, 29.6.2013, p. 19).

- (27) The threshold of EUR 50 000 laid down in Article 45(1) of Directive 2006/43/EC was aligned on points (c) and (d) of Article 3(2) of Directive 2003/71/EC of the European Parliament and of the Council ⁽¹⁾. The thresholds set out in Directive 2003/71/EC have been increased to EUR 100 000 by Article 1(3) of Directive 2010/73/EU of the European Parliament and of the Council ⁽²⁾. For that reason, corresponding adjustments should be made to the threshold set out in Article 45(1) of Directive 2006/43/EC.
- (28) In order to give full effect to the new legal framework provided for in the TFEU, it is necessary to adapt and replace the implementing powers provided for under Article 202 of the Treaty establishing the European Community with the appropriate provisions in accordance with Articles 290 and 291 TFEU.
- (29) The alignment of the procedures for the adoption of delegated and implementing acts by the Commission to the TFEU and, in particular, to Articles 290 and 291 thereof, should be done on a case-by-case basis. In order to take into account the developments in auditing and the audit profession, and to facilitate the oversight of statutory auditors and audit firms, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. In the field of auditor oversight, the use of delegated acts is necessary in order to develop the procedures for cooperation between the competent authorities of Member States and those of third countries. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (30) In order to ensure uniform conditions for the implementation of the declarations on the equivalence of third-country auditor oversight regimes or the adequacy of third-country competent authorities, in so far as they concern individual third countries or individual competent authorities of third countries, 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 ⁽³⁾.
- (31) Since the objective of this Directive, namely to reinforce investor confidence in the truth and fairness of the financial statements published by undertakings by further enhancing the quality of statutory audits that are performed within the Union, cannot be sufficiently achieved by Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (32) Directive 2006/43/EC should therefore be amended accordingly.
- (33) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 of the European Parliament and of the Council ⁽⁴⁾ and delivered an opinion on 23 April 2012 ⁽⁵⁾.
- (34) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents ⁽⁶⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified,

⁽¹⁾ 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 and amending Directive 2001/34/EC (OJ L 345, 31.12.2003, p. 64).

⁽²⁾ Directive 2010/73/EU of the European Parliament and of the Council of 24 November 2010 amending Directives 2003/71/EC on the prospectus to be published when securities are offered to the public or admitted to trading and 2004/109/EC on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market (OJ L 327, 11.12.2010, p. 1).

⁽³⁾ 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 power (OJ L 55, 28.2.2011, p. 13).

⁽⁴⁾ 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 (OJ L 8, 12.1.2001, p. 1).

⁽⁵⁾ OJ C 336, 6.11.2012, p. 4.

⁽⁶⁾ OJ C 369, 17.12.2011, p. 14.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2006/43/EC is hereby amended as follows:

1. In Article 1 the following paragraph is added:

‘Article 29 of this Directive shall not apply to the statutory audit of annual and consolidated financial statements of public-interest entities unless specified in Regulation (EU) No 537/2014 of the European Parliament and the Council (*).

(*) Regulation (EU) No 537/2014 of the European Parliament and of the Council of 16 April 2014 on specific requirements regarding statutory audit of public-interest entities (OJ L 158, 27.5.2014, p. 77).’

2. Article 2 is amended as follows:

(a) point 1 is replaced by the following:

‘1. “statutory audit” means an audit of annual financial statements or consolidated financial statements in so far as:

(a) required by Union law;

(b) required by national law as regards small undertakings;

(c) voluntarily carried out at the request of small undertakings which meets national legal requirements that are equivalent to those for an audit under point (b), where national legislation defines such audits as statutory audits;’

(b) point 4 is replaced by the following:

‘4. “third-country audit entity” means an entity, regardless of its legal form, which carries out audits of the annual or consolidated financial statements of a company incorporated in a third country, other than an entity which is registered as an audit firm in any Member State as a consequence of approval in accordance with Article 3;’

(c) point 5 is replaced by the following:

‘5. “third-country auditor” means a natural person who carries out audits of the annual or consolidated financial statements of a company incorporated in a third country, other than a person who is registered as a statutory auditor in any Member State as a consequence of approval in accordance with Articles 3 and 44;’

(d) point 10 is replaced by the following:

‘10. “competent authorities” means the authorities designated by law that are in charge of the regulation and/or oversight of statutory auditors and audit firms or of specific aspects thereof; the reference to “competent authority” in a specific Article means a reference to the authority responsible for the functions referred to in that Article;’

(e) point 11 is deleted;

(f) point 13 is replaced by the following:

‘13. “public-interest entities” means:

(a) entities governed by the law of a Member State whose transferable securities are admitted to trading on a regulated market of any Member State within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC;

(b) credit institutions as defined in point 1 of Article 3(1) of Directive 2013/36/EU of the European Parliament and of the Council (**), other than those referred to in Article 2 of that Directive;

- (c) insurance undertakings within the meaning of Article 2(1) of Directive 91/674/EEC; or
- (d) entities designated by Member States as public-interest entities, for instance undertakings that are of significant public relevance because of the nature of their business, their size or the number of their employees;

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

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

'15. "non-practitioner" means any natural person who, during his or her involvement in the governance of the public oversight system and during the period of three years immediately preceding that involvement, has not carried out statutory audits, has not held voting rights in an audit firm, has not been a member of the administrative, management or supervisory body of an audit firm and has not been employed by, or otherwise associated with, an audit firm;'

- (h) the following points 17 to 20 are added:

'17. "medium-sized undertakings" means the undertakings referred to in Article 1(1) and Article 3(3) of Directive 2013/34/EU of the European Parliament and of the Council (*);

18. "small undertakings" means the undertakings referred to in Article 1(1) and Article 3(2) of Directive 2013/34/EU;

19. "home Member State" means a Member State in which a statutory auditor or audit firm is approved in accordance with Article 3(1);

20. "host Member State" means a Member State in which a statutory auditor approved by his or her home Member State seeks to be also approved in accordance with Article 14, or a Member State in which an audit firm approved by its home Member State seeks to be registered or is registered in accordance with Article 3a.

(*) Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013 on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings, amending Directive 2006/43/EC of the European Parliament and of the Council and repealing Council Directives 78/660/EEC and 83/349/EEC (OJ L 182, 29.6.2013, p. 19).'

- 3. Article 3 is amended as follows:

- (a) paragraph 2 is amended as follows:

- (i) the first subparagraph is replaced by the following:

'Each Member State shall designate the competent authority to be responsible for approving statutory auditors and audit firms.'

- (ii) the second subparagraph is deleted;

- (b) point (b) of the first subparagraph of paragraph 4 is replaced by the following:

'(b) a majority of the voting rights in an entity must be held by audit firms which are approved in any Member State or by natural persons who satisfy at least the conditions imposed by Articles 4 and 6 to 12. Member States may provide that such natural persons must also have been approved in another Member State. For the purpose of the statutory audit of cooperatives, savings banks and similar entities as referred to in Article 45 of Directive 86/635/EEC, a subsidiary or legal successor of a cooperative, savings bank or similar entity as referred to in Article 45 of Directive 86/635/EEC, Member States may lay down other specific provisions in relation to voting rights;'

4. The following Article is inserted:

'Article 3a

Recognition of audit firms

1. By way of derogation from Article 3(1), an audit firm which is approved in a Member State shall be entitled to perform statutory audits in another Member State provided that the key audit partner who carries out the statutory audit on behalf of the audit firm complies with point (a) of Article 3(4) in the host Member State.

2. An audit firm that wishes to carry out statutory audits in a Member State other than its home Member State shall register with the competent authority in the host Member State in accordance with Articles 15 and 17.

3. The competent authority in the host Member State shall register the audit firm if it is satisfied that the audit firm is registered with the competent authority in the home Member State. Where the host Member State intends to rely on a certificate attesting to the registration of the audit firm in the home Member State, the competent authority in the host Member State may require that the certificate issued by the competent authority in the home Member State be not more than three months old. The competent authority in the host Member State shall inform the competent authority in the home Member State of the registration of the audit firm.'

5. In Article 5, paragraph 3 is replaced by the following:

'3. Where the approval of a statutory auditor or of an audit firm is withdrawn for any reason, the competent authority of the home Member State where the approval is withdrawn shall communicate that fact and the reasons for the withdrawal to the relevant competent authorities of host Member States where the statutory auditor or the audit firm is also registered in accordance with Article 3a, point (c) of Article 16(1) and point (i) of Article 17(1).'

6. In Article 6, the following paragraph is added:

'The competent authorities referred to in Article 32 shall cooperate with each other with a view to achieving a convergence of the requirements set out in this Article. When engaging in such cooperation, those competent authorities shall take into account developments in auditing and in the audit profession and, in particular, convergence that has already been achieved by the profession. They shall cooperate with the Committee of European Auditing Oversight Bodies (CEAOB) and the competent authorities referred to in Article 20 of Regulation (EU) No 537/2014 in so far as such convergence relates to the statutory audit of public-interest entities.'

7. Article 8 is amended as follows:

(a) in paragraph 1, point (i) is replaced by the following:

'(i) international auditing standards as referred to in Article 26;'

(b) paragraph 3 is deleted.

8. In Article 10, paragraph 1 is replaced by the following:

'1. In order to ensure the ability to apply theoretical knowledge in practice, a test of which is included in the examination, a trainee shall complete a minimum of three years' practical training in, inter alia, the auditing of annual financial statements, consolidated financial statements or similar financial statements. At least two thirds of such practical training shall be completed with a statutory auditor or an audit firm approved in any Member State.'

9. Article 13 is replaced by the following:

'Article 13

Continuing education

Member States shall ensure that statutory auditors are required to take part in appropriate programmes of continuing education in order to maintain their theoretical knowledge, professional skills and values at a sufficiently high level, and that failure to respect the continuing education requirements is subject to appropriate sanctions as referred to in Article 30.'

10. Article 14 is replaced by the following:

'Article 14

Approval of statutory auditors from another Member State

1. The competent authorities shall establish procedures for the approval of statutory auditors who have been approved in other Member States. Those procedures shall not go beyond the requirement to complete an adaptation period as defined in point (g) of Article 3(1) of Directive 2005/36/EC of the European Parliament and of the Council (*) or to pass an aptitude test as defined in point (h) of that provision.

2. The host Member State shall decide whether the applicant seeking approval is to be subject to an adaptation period as defined in point (g) of Article 3(1) of Directive 2005/36/EC or an aptitude test as defined in point (h) of that provision.

The adaptation period shall not exceed three years and the applicant shall be subject to an assessment.

The aptitude test shall be conducted in one of the languages permitted by the language rules applicable in the host Member State concerned. It shall cover only the statutory auditor's adequate knowledge of the laws and regulations of that host Member State in so far as it is relevant to statutory audits.

3. The competent authorities shall cooperate within the framework of the CEAOB with a view to achieving a convergence of the requirements of the adaptation period and the aptitude test. They shall enhance the transparency and predictability of the requirements. They shall cooperate with the CEAOB and with the competent authorities referred to in Article 20 of Regulation (EU) No 537/2014 in so far as such convergence relates to statutory audits of public-interest entities.

(*) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).'

11. In Article 15, paragraph 1 is replaced by the following:

'1. Each Member State shall ensure that statutory auditors and audit firms are entered in a public register in accordance with Articles 16 and 17. In exceptional circumstances, Member States may derogate from the requirements laid down in this Article and Article 16 regarding disclosure only to the extent necessary to mitigate an imminent and significant threat to the personal security of any person.'

12. In Article 17(1), the following point is added:

'(j) where applicable, whether the audit firm is registered pursuant to Article 3a(3).'

13. Article 21 is amended as follows:

(a) the title is replaced by the following:

'Professional ethics and scepticism'

(b) paragraph 2 is replaced by the following:

'2. Member States shall ensure that, when the statutory auditor or the audit firm carries out the statutory audit, he, she or it maintains professional scepticism throughout the audit, recognising the possibility of a material misstatement due to facts or behaviour indicating irregularities, including fraud or error, notwithstanding the statutory auditor's or the audit firm's past experience of the honesty and integrity of the audited entity's management and of the persons charged with its governance.

The statutory auditor or the audit firm shall maintain professional scepticism in particular when reviewing management estimates relating to fair values, the impairment of assets, provisions, and future cash flow relevant to the entity's ability to continue as a going concern.

For the purposes of this Article, "professional scepticism" means an attitude that includes a questioning mind, being alert to conditions which may indicate possible misstatement due to error or fraud, and a critical assessment of audit evidence.'

14. Article 22 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Member States shall ensure that, when carrying out a statutory audit, a statutory auditor or an audit firm, and any natural person in a position to directly or indirectly influence the outcome of the statutory audit, is independent of the audited entity and is not involved in the decision-taking of the audited entity.

Independence shall be required at least during both the period covered by the financial statements to be audited and the period during which the statutory audit is carried out.

Member States shall ensure that a statutory auditor or an audit firm takes all reasonable steps to ensure that, when carrying out a statutory audit, his, her or its independence is not affected by any existing or potential conflict of interest or business or other direct or indirect relationship involving the statutory auditor or the audit firm carrying out the statutory audit and, where appropriate, its network, managers, auditors, employees, any other natural persons whose services are placed at the disposal or under the control of the statutory auditor or the audit firm, or any person directly or indirectly linked to the statutory auditor or the audit firm by control.

The statutory auditor or the audit firm shall not carry out a statutory audit if there is any threat of self-review, self-interest, advocacy, familiarity or intimidation created by financial, personal, business, employment or other relationships between:

- the statutory auditor, the audit firm, its network, and any natural person in a position to influence the outcome of the statutory audit, and
- the audited entity,

as a result of which an objective, reasonable and informed third party, taking into account the safeguards applied, would conclude that the statutory auditor's or the audit firm's independence is compromised.'

(b) paragraph 2 is replaced by the following:

'2. Member States shall ensure that a statutory auditor, an audit firm, their key audit partners, their employees, and any other natural person whose services are placed at the disposal or under the control of such statutory auditor or audit firm and who is directly involved in statutory audit activities, and persons closely associated with them within the meaning of Article 1(2) of Commission Directive 2004/72/EC (*), do not hold or have a material and direct beneficial interest in, or engage in any transaction in any financial instrument issued, guaranteed, or otherwise supported by, any audited entity within their area of statutory audit activities, other than interests owned indirectly through diversified collective investment schemes, including managed funds such as pension funds or life insurance.

(*) Commission Directive 2004/72/EC of 29 April 2004 implementing Directive 2003/6/EC of the European Parliament and of the Council as regards accepted market practices, the definition of inside information in relation to derivatives on commodities, the drawing up of lists of insiders, the notification of managers' transactions and the notification of suspicious transactions (OJ L 162, 30.4.2004, p. 70).'

(c) paragraph 4 is replaced by the following:

'4. Member States shall ensure that persons or firms referred to in paragraph 2 do not participate in or otherwise influence the outcome of a statutory audit of any particular audited entity if they:

- (a) own financial instruments of the audited entity, other than interests owned indirectly through diversified collective investment schemes;
- (b) own financial instruments of any entity related to an audited entity, the ownership of which may cause, or may be generally perceived as causing, a conflict of interest, other than interests owned indirectly through diversified collective investment schemes;
- (c) have had an employment, or a business or other relationship with that audited entity within the period referred in paragraph 1 that may cause, or may be generally perceived as causing, a conflict of interest.'

(d) the following paragraphs are added:

‘5. Persons or firms referred to in paragraph 2 shall not solicit or accept pecuniary and non-pecuniary gifts or favours from the audited entity or any entity related to an audited entity unless an objective, reasonable and informed third party would consider the value thereof as trivial or inconsequential.

6. If, during the period covered by the financial statements, an audited entity is acquired by, merges with, or acquires another entity, the statutory auditor or the audit firm shall identify and evaluate any current or recent interests or relationships, including any non-audit services provided to that entity, which, taking into account available safeguards, could compromise the auditor’s independence and ability to continue with the statutory audit after the effective date of the merger or acquisition.

As soon as possible, and in any event within three months, the statutory auditor or the audit firm shall take all such steps as may be necessary to terminate any current interests or relationships that would compromise its independence and shall, where possible, adopt safeguards to minimise any threat to its independence arising from prior and current interests and relationships.’

15. The following Article is inserted:

‘Article 22a

Employment by audited entities of former statutory auditors or of employees of statutory auditors or audit firms

1. Member States shall ensure that a statutory auditor or a key audit partner who carries out a statutory audit on behalf of an audit firm does not, before a period of at least one year, or in the case of statutory audit of public-interest entities a period of at least two years, has elapsed since he or she ceased to act as a statutory auditor or key audit partner in connection with the audit engagement:

- (a) take up a key management position in the audited entity;
- (b) where applicable, become a member of the audit committee of the audited entity or, where such committee does not exist, of the body performing equivalent functions to an audit committee;
- (c) become a non-executive member of the administrative body or a member of the supervisory body of the audited entity.

2. Member States shall ensure that employees and partners other than key audit partners of a statutory auditor or of an audit firm carrying out a statutory audit, as well as any other natural person whose services are placed at the disposal or under the control of such statutory auditor or audit firm, do not, when such employees, partners or other natural persons are personally approved as statutory auditors, take up any of the duties referred to in points (a), (b) and (c) of paragraph 1 before a period of at least one year has elapsed since he or she was directly involved in the statutory audit engagement.’

16. The following Article is inserted:

‘Article 22b

Preparation for the statutory audit and assessment of threats to independence

Member States shall ensure that, before accepting or continuing an engagement for a statutory audit, a statutory auditor or an audit firm assesses and documents the following:

- whether he, she or it complies with the requirements of Article 22 of this Directive;
- whether there are threats to his, her or its independence and the safeguards applied to mitigate those threats;

- whether he, she or it has the competent employees, time and resources needed in order to carry out the statutory audit in an appropriate manner;
- whether, in the case of an audit firm, the key audit partner is approved as statutory auditor in the Member State requiring the statutory audit;

Member States may provide simplified requirements for the audits referred in points (b) and (c) of point 1 of Article 2.'

17. Article 23 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. Confidentiality and professional secrecy rules relating to statutory auditors or audit firms shall not impede enforcement of the provisions of this Directive or of Regulation (EU) No 537/2014;'

(b) paragraph 3 is replaced by the following:

'3. Where a statutory auditor or an audit firm is replaced by another statutory auditor or audit firm, the former statutory auditor or audit firm shall provide the incoming statutory auditor or audit firm with access to all relevant information concerning the audited entity and the most recent audit of that entity;'

(c) the following paragraph is added:

'5. Where a statutory auditor or an audit firm carries out a statutory audit of an undertaking which is part of a group whose parent undertaking is situated in a third country, the confidentiality and professional secrecy rules referred to in paragraph 1 of this Article shall not impede the transfer by the statutory auditor or the audit firm of relevant documentation concerning the audit work performed to the group auditor situated in a third country if such documentation is necessary for the performance of the audit of consolidated financial statements of the parent undertaking.'

A statutory auditor or an audit firm that carries out the statutory audit of an undertaking which has issued securities in a third country, or which forms part of a group issuing statutory consolidated financial statements in a third country, may only transfer the audit working papers or other documents relating to the audit of that entity that he, she or it holds to the competent authorities in the relevant third countries under the conditions set out in Article 47.

The transfer of information to the group auditor situated in a third country shall comply with Chapter IV of Directive 95/46/EC and the applicable national rules on personal data protection.'

18. The following Article is inserted:

'Article 24a

Internal organisation of statutory auditors and audit firms

1. Member States shall ensure that a statutory auditor or an audit firm complies with the following organisational requirements:

- (a) an audit firm shall establish appropriate policies and procedures to ensure that its owners or shareholders, as well as the members of the administrative, management and supervisory bodies of the firm, or of an affiliate firm, do not intervene in the carrying-out of a statutory audit in any way which jeopardises the independence and objectivity of the statutory auditor who carries out the statutory audit on behalf of the audit firm;
- (b) a statutory auditor or an audit firm shall have sound administrative and accounting procedures, internal quality control mechanisms, effective procedures for risk assessment, and effective control and safeguard arrangements for information processing systems.

Those internal quality control mechanisms shall be designed to secure compliance with decisions and procedures at all levels of the audit firm or of the working structure of the statutory auditor;

- (c) a statutory auditor or an audit firm shall establish appropriate policies and procedures to ensure that his, her or its employees and any other natural persons whose services are placed at his, her or its disposal or under his, her or its control, and who are directly involved in the statutory audit activities, have appropriate knowledge and experience for the duties assigned;
- (d) a statutory auditor or an audit firm shall establish appropriate policies and procedures to ensure that outsourcing of important audit functions is not undertaken in such a way as to impair the quality of the statutory auditor's or the audit firm's internal quality control and the ability of the competent authorities to supervise the statutory auditor's or the audit firm's compliance with the obligations laid down in this Directive and, where applicable, in Regulation (EU) No 537/2014;
- (e) a statutory auditor or an audit firm shall establish appropriate and effective organisational and administrative arrangements to prevent, identify, eliminate or manage and disclose any threats to their independence as referred to in 22, 22a and 22b;
- (f) a statutory auditor or an audit firm shall establish appropriate policies and procedures for carrying out statutory audits, coaching, supervising and reviewing employees activities and organising the structure of the audit file as referred to in Article 24b(5);
- (g) a statutory auditor or an audit firm shall establish an internal quality control system to ensure the quality of the statutory audit.

The quality control system shall at least cover the policies and procedures described in point (f). In the case of an audit firm, responsibility for the internal quality control system shall lie with a person who is qualified as a statutory auditor;

- (h) a statutory auditor or an audit firm shall use appropriate systems, resources and procedures to ensure continuity and regularity in the carrying out of his, her or its statutory audit activities;
- (i) a statutory auditor or an audit firm shall also establish appropriate and effective organisational and administrative arrangements for dealing with and recording incidents which have, or may have, serious consequences for the integrity of his, her or its statutory audit activities;
- (j) a statutory auditor or an audit firm shall have in place adequate remuneration policies, including profit-sharing policies, providing sufficient performance incentives to secure audit quality. In particular, the amount of revenue that the statutory auditor or the audit firm derives from providing non-audit services to the audited entity shall not form part of the performance evaluation and remuneration of any person involved in, or able to influence the carrying out of, the audit;
- (k) a statutory auditor or an audit firm shall monitor and evaluate the adequacy and effectiveness of his, her or its systems, internal quality control mechanisms and arrangements established in accordance with this Directive and, where applicable, Regulation (EU) No 537/2014 and take appropriate measures to address any deficiencies. A statutory auditor or an audit firm shall in particular carry out an annual evaluation of the internal quality control system, referred to in point (g). A statutory auditor or an audit firm shall keep records of the findings of that evaluation and any proposed measure to modify the internal quality control system.

The policies and procedures referred to in the first subparagraph shall be documented and communicated to the employees of the statutory auditor or the audit firm.

Member States may provide simplified requirements for the audits referred in points (b) and (c) of point 1 of Article 2.

Any outsourcing of audit functions as referred to in point (d) of this paragraph shall not affect the responsibility of the statutory auditor or the audit firm towards the audited entity.

2. The statutory auditor or the audit firm shall take into consideration the scale and complexity of his, her or its activities when complying with the requirements set out in paragraph 1 of this Article.

The statutory auditor or the audit firm shall be able to demonstrate to the competent authority that the policies and procedures designed to achieve such compliance are appropriate given the scale and complexity of activities of the statutory auditor or the audit firm.'

19. The following Article is inserted:

'Article 24b

Organisation of the work

1. Member States shall ensure that, when the statutory audit is carried out by an audit firm, that audit firm designates at least one key audit partner. The audit firm shall provide the key audit partner(s) with sufficient resources and with personnel that have the necessary competence and capabilities to carry out his, her or its duties appropriately.

Securing audit quality, independence and competence shall be the main criteria when the audit firm selects the key audit partner(s) to be designated.

The key audit partner(s) shall be actively involved in the carrying-out of the statutory audit.

2. When carrying out the statutory audit, the statutory auditor shall devote sufficient time to the engagement and shall assign sufficient resources to enable him or her to carry out his or her duties appropriately.

3. Member States shall ensure that the statutory auditor or the audit firm keeps records of any breaches of the provisions of this Directive and, where applicable, of Regulation (EU) No 537/2014. Member States may exempt statutory auditors and audit firms from this obligation with regard to minor breaches. Statutory auditors and audit firms shall also keep records of any consequence of any breach, including the measures taken to address such breach and to modify their internal quality control system. They shall prepare an annual report containing an overview of any such measures taken and shall communicate that report internally.

When a statutory auditor or an audit firm asks external experts for advice, he, she or it shall document the request made and the advice received.

4. A statutory auditor or an audit firm shall maintain a client account record. Such record shall include the following data for each audit client:

- (a) the name, the address and the place of business;
- (b) in the case of an audit firm, the name(s) of the key audit partner(s);
- (c) the fees charged for the statutory audit and the fees charged for other services in any financial year.

5. A statutory auditor or an audit firm shall create an audit file for each statutory audit.

The statutory auditor or the audit firm shall document at least the data recorded pursuant to Article 22b(1) of this Directive, and, where applicable, Articles 6 to 8 of Regulation (EU) No 537/2014.

The statutory auditor or the audit firm shall retain any other data and documents that are of importance in support of the report referred to in Articles 28 of this Directive and, where applicable, Articles 10 and 11 of Regulation (EU) No 537/2014 and for monitoring compliance with this Directive and other applicable legal requirements.

The audit file shall be closed no later than 60 days after the date of signature of the audit report referred to in Article 28 of this Directive and, where applicable, Article 10 of Regulation (EU) No 537/2014.

6. The statutory auditor or the audit firm shall keep records of any complaints made in writing about the performance of the statutory audits carried out.

7. Member States may lay down simplified requirements with regard to paragraphs 3 and 6 for the audits referred to in points (b) and (c) of point 1 of Article 2.'

20. The following Article is inserted:

'Article 25a

Scope of the statutory audit

Without prejudice to the reporting requirements referred to in Article 28 of this Directive and, where applicable, Articles 10 and 11 of Regulation (EU) No 537/2014, the scope of the statutory audit shall not include assurance on the future viability of the audited entity or on the efficiency or effectiveness with which the management or administrative body has conducted or will conduct the affairs of the entity.'

21. Article 26 is replaced by the following:

'Article 26

Auditing standards

1. Member States shall require statutory auditors and audit firms to carry out statutory audits in compliance with international auditing standards adopted by the Commission in accordance with paragraph 3.

Member States may apply national auditing standards, procedures or requirements as long as the Commission has not adopted an international auditing standard covering the same subject-matter.

2. For the purposes of paragraph 1, "international auditing standards" means International Standards on Auditing (ISAs), International Standard on Quality Control (ISQC 1) and other related Standards issued by the International Federation of Accountants (IFAC) through the International Auditing and Assurance Standards Board (IAASB), in so far as they are relevant to the statutory audit.

3. The Commission shall be empowered to adopt, by means of delegated acts in accordance with Article 48a, the international auditing standards referred to in paragraph 1 in the area of audit practice, independence and internal quality controls of statutory auditors and audit firms for the purposes of the application of those standards within the Union.

The Commission may adopt the international auditing standards only if they:

- (a) have been developed with proper due process, public oversight and transparency, and are generally accepted internationally;
- (b) contribute a high level of credibility and quality to the annual or consolidated financial statements in conformity with the principles set out in Article 4(3) of Directive 2013/34/EC;
- (c) are conducive to the Union public good; and
- (d) do not amend any of the requirements of this Directive or supplement any of its requirements apart from those set out in Chapter IV and Articles 27 and 28.

4. Notwithstanding the second subparagraph of paragraph 1, Member States may impose audit procedures or requirements in addition to the international auditing standards adopted by the Commission, only

- (a) if those audit procedures or requirements are necessary in order to give effect to national legal requirements relating to the scope of statutory audits; or
- (b) to the extent necessary to add to the credibility and quality of financial statements.

Member States shall communicate the audit procedures or requirements to the Commission at least three months before their entry into force or, in the case of requirements already existing at the time of adoption of an international auditing standard, at the latest within three months of the adoption of the relevant international auditing standard.

5. Where a Member State requires the statutory audit of small undertakings, it may provide that application of the auditing standards referred to in paragraph 1 is to be proportionate to the scale and complexity of the activities of such undertakings. Member States may take measures in order to ensure the proportionate application of the auditing standards to the statutory audits of small undertakings.'

22. Article 27 is replaced by the following:

'Article 27

Statutory audits of consolidated financial statements

1. Member States shall ensure that in the case of a statutory audit of the consolidated financial statements of a group of undertakings:

- (a) in relation to the consolidated financial statements, the group auditor bears the full responsibility for the audit report referred to in Article 28 of this Directive and, where applicable, Article 10 of Regulation (EU) No 537/2014 and for, where applicable, the additional report to the audit committee as referred to in Article 11 of that Regulation;
- (b) the group auditor evaluates the audit work performed by any third-country auditor(s) or statutory auditor(s) and third-country audit entity(ies), or audit firm(s) for the purpose of the group audit, and documents the nature, timing and extent of the work performed by those auditors, including, where applicable, the group auditor's review of relevant parts of those auditors' audit documentation;
- (c) the group auditor reviews the audit work performed by third-country auditor(s) or statutory auditor(s) and third-country audit entity(ies) or audit firm(s) for the purpose of the group audit and documents it.

The documentation retained by the group auditor shall be such as to enable the relevant competent authority to review the work of the group auditor.

For the purposes of point (c) of the first subparagraph of this paragraph, the group auditor shall request the agreement of the third-country auditor(s), statutory auditor(s), third-country audit entity(ies) or audit firm(s) concerned to the transfer of relevant documentation during the conduct of the audit of consolidated financial statements, as a condition of the reliance by the group auditor on the work of those third-country auditor(s), statutory auditor(s), third-country audit entity(ies) or audit firm(s).

2. Where the group auditor is unable to comply with point (c) of the first subparagraph of paragraph 1, he, she or it shall take appropriate measures and inform the relevant competent authority.

Such measures shall, as appropriate, include carrying out additional statutory audit work, either directly or by outsourcing such tasks, in the relevant subsidiary.

3. Where the group auditor is subject to a quality assurance review or an investigation concerning the statutory audit of the consolidated financial statements of a group of undertakings, the group auditor shall, when requested, make available to the competent authority the relevant documentation he, she or it retains concerning the audit work performed by the respective third-country auditor(s), statutory auditor(s), third-country audit entity(ies) or audit firm(s) for the purpose of the group audit, including any working papers relevant to the group audit.

The competent authority may request additional documentation on the audit work performed by any statutory auditor(s) or audit firm(s) for the purpose of the group audit from the relevant competent authorities pursuant to Article 36.

Where a parent undertaking or a subsidiary undertaking of a group of undertakings is audited by an auditor or auditor(s) or an audit entity(ies) from a third country, the competent authority may request additional documentation on the audit work performed by any third-country auditor(s) or third country audit entity(ies) from the relevant competent authorities from third countries through the working arrangements referred to in Article 47.

By way of derogation from the third subparagraph, where a parent undertaking or a subsidiary undertaking of a group of undertakings is audited by an auditor or auditors or an audit entity or entities from a third country that has no working arrangements as referred to in Article 47, the group auditor shall, when requested, also be responsible for ensuring proper delivery of the additional documentation of the audit work performed by such third-country auditor(s) or audit entity(ies), including the working papers relevant to the group audit. In order to ensure such delivery, the group auditor shall retain a copy of such documentation, or alternatively agree with the third-country auditor(s) or audit entity(ies) that he, she or it is to be given unrestricted access to such documentation upon request, or take any other appropriate action. Where audit working papers cannot, for legal or other reasons, be passed from a third country to the group auditor, the documentation retained by the group auditor shall include evidence that he or she has undertaken the appropriate procedures in order to gain access to the audit documentation, and in the case of impediments other than legal ones arising from the legislation of the third country concerned, evidence supporting the existence of such impediments.'

23. Article 28 is replaced by the following:

Article 28

Audit reporting

1. The statutory auditor(s) or the audit firm(s) shall present the results of the statutory audit in an audit report. The report shall be prepared in accordance with the requirements of auditing standards adopted by the Union or Member State concerned, as referred to in Article 26.

2. The audit report shall be in writing and shall:

- (a) identify the entity whose annual or consolidated financial statements are the subject of the statutory audit; specify the annual or consolidated financial statements and the date and period they cover; and identify the financial reporting framework that has been applied in their preparation;
- (b) include a description of the scope of the statutory audit which shall, as a minimum, identify the auditing standards in accordance with which the statutory audit was conducted;
- (c) include an audit opinion, which shall be either unqualified, qualified or an adverse opinion and shall state clearly the opinion of the statutory auditor(s) or the audit firm(s) as to:
 - (i) whether the annual financial statements give a true and fair view in accordance with the relevant financial reporting framework; and,
 - (ii) where appropriate, whether the annual financial statements comply with statutory requirements.

If the statutory auditor(s) or the audit firm(s) are unable to express an audit opinion, the report shall contain a disclaimer of opinion;

- (d) refer to any other matters to which the statutory auditor(s) or the audit firm(s) draw(s) attention by way of emphasis without qualifying the audit opinion;
- (e) include an opinion and statement, both of which shall be based on the work undertaken in the course of the audit, referred to in the second subparagraph of Article 34(1) of Directive 2013/34/EU;
- (f) provide a statement on any material uncertainty relating to events or conditions that may cast significant doubt about the entity's ability to continue as a going concern;
- (g) identify the place of establishment of the statutory auditor(s) or the audit firm(s).

Member States may lay down additional requirements in relation to the content of the audit report.

3. Where the statutory audit was carried out by more than one statutory auditor or audit firm, the statutory auditor(s) or the audit firm(s) shall agree on the results of the statutory audit and submit a joint report and opinion. In the case of disagreement, each statutory auditor or audit firm shall submit his, her or its opinion in a separate paragraph of the audit report and shall state the reason for the disagreement.

4. The audit report shall be signed and dated by the statutory auditor. Where an audit firm carries out the statutory audit, the audit report shall bear the signature of at least the statutory auditor(s) carrying out the statutory audit on behalf of the audit firm. Where more than one statutory auditor or audit firm have been simultaneously engaged, the audit report shall be signed by all statutory auditors or at least by the statutory auditors carrying out the statutory audit on behalf of every audit firm. In exceptional circumstances Member States may provide that such signature(s) need not be disclosed to the public if such disclosure could lead to an imminent and significant threat to the personal security of any person.

In any event, the name(s) of the person(s) involved shall be known to the relevant competent authorities.

5. The report of the statutory auditor or the audit firm on the consolidated financial statements shall comply with the requirements set out in paragraphs 1 to 4. In reporting on the consistency of the management report and the financial statements as required by point (e) of paragraph 2, the statutory auditor or the audit firm shall consider the consolidated financial statements and the consolidated management report. Where the annual financial statements of the parent undertaking are attached to the consolidated financial statements, the reports of the statutory auditors or the audit firms required by this Article may be combined.'

24. Article 29 is amended as follows:

(a) paragraph 1 is amended as follows:

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

'(a) the quality assurance system shall be organised in such a manner that it is independent of the reviewed statutory auditors and audit firms and is subject to public oversight;'

(ii) point (h) is replaced by the following:

'(h) quality assurance reviews shall take place on the basis of an analysis of the risk and, in the case of statutory auditors and audit firms carrying out statutory audits as defined in point (a) of point 1 of Article 2, at least every six years;'

(iii) the following point is added:

'(k) quality assurance reviews shall be appropriate and proportionate in view of the scale and complexity of the activity of the reviewed statutory auditor or audit firm.';

(b) paragraph 2 is replaced by the following:

'2. For the purpose of point (e) of paragraph 1, at least the following criteria shall apply to the selection of reviewers:

(a) reviewers shall have appropriate professional education and relevant experience in statutory audit and financial reporting combined with specific training on quality assurance reviews;

(b) a person shall not be allowed to act as a reviewer in a quality assurance review of a statutory auditor or an audit firm until at least three years have elapsed since that person ceased to be a partner or an employee of, or otherwise associated with, that statutory auditor or audit firm;

(c) reviewers shall declare that there are no conflicts of interest between them and the statutory auditor and the audit firm to be reviewed.'

(c) the following paragraph is added:

'3. For the purpose of point (k) of paragraph 1, Member States shall require competent authorities, when undertaking quality assurance reviews of the statutory audits of annual or consolidated financial statements of medium-sized and small undertakings, to take account of the fact that the auditing standards adopted in accordance with Article 26 are designed to be applied in a manner that is proportionate to the scale and complexity of the business of the audited entity.'

25. Chapter VII is replaced by the following:

‘CHAPTER VII

INVESTIGATIONS AND SANCTIONS

Article 30

Systems of investigations and sanctions

1. Member States shall ensure that there are effective systems of investigations and sanctions to detect, correct and prevent inadequate execution of the statutory audit.

2. Without prejudice to Member States' civil liability regimes, Member States shall provide for effective, proportionate and dissuasive sanctions in respect of statutory auditors and audit firms, where statutory audits are not carried out in conformity with the provisions adopted in the implementation of this Directive, and, where applicable, Regulation (EU) No 537/2014.

Member States may decide not to lay down rules for administrative sanctions for infringements which are already subject to national criminal law. In that event, they shall communicate to the Commission the relevant criminal law provisions.

3. Member States shall provide that measures taken and sanctions imposed on statutory auditors and audit firms are to be appropriately disclosed to the public. Sanctions shall include the possibility of withdrawal of approval. Member States may decide that such disclosure shall not contain personal data within the meaning of point (a) of Article 2 of Directive 95/46/EC.

4. By 17 June 2016 the Member States shall notify the rules referred to in paragraph 2 to the Commission. They shall notify the Commission without delay of any subsequent amendment thereto.

Article 30a

Sanctioning powers

1. Member States shall provide for competent authorities to have the power to take and/or impose at least the following administrative measures and sanctions for breaches of the provisions of this Directive and, where applicable, of Regulation (EU) No 537/2014:

- (a) a notice requiring the natural or legal person responsible for the breach to cease the conduct and to abstain from any repetition of that conduct;
- (b) a public statement which indicates the person responsible and the nature of the breach, published on the website of competent authorities;
- (c) a temporary prohibition, of up to three years' duration, banning the statutory auditor, the audit firm or the key audit partner from carrying out statutory audits and/or signing audit reports;
- (d) a declaration that the audit report does not meet the requirements of Article 28 of this Directive or, where applicable, Article 10 of Regulation (EU) No 537/2014;
- (e) a temporary prohibition, of up to three years' duration, banning a member of an audit firm or a member of an administrative or management body of a public-interest entity from exercising functions in audit firms or public-interest entities;
- (f) the imposition of administrative pecuniary sanctions on natural and legal persons.

2. Member States shall ensure that the competent authorities are able to exercise their sanctioning powers in accordance with this Directive and national law and in any of the following ways:

- (a) directly;
- (b) in collaboration with other authorities;
- (c) by application to the competent judicial authorities.

3. Member States may confer on competent authorities other sanctioning powers in addition to those referred to in paragraph 1.

4. By way of derogation from paragraph 1, Member States may confer on authorities supervising public-interest entities, when they are not designated as the competent authority pursuant to Article 20(2) of Regulation (EU) No 537/2014, powers to impose sanctions for breaches of reporting duties provided for by that Regulation.

Article 30b

Effective application of sanctions

When laying down rules pursuant to Article 30, Member States shall require that, when determining the type and level of administrative sanctions and measures, competent authorities are to take into account all relevant circumstances, including where appropriate:

- (a) the gravity and the duration of the breach;
- (b) the degree of responsibility of the responsible person;
- (c) the financial strength of the responsible person, for example as indicated by the total turnover of the responsible undertaking or the annual income of the responsible person, if that person is a natural person;
- (d) the amounts of the profits gained or losses avoided by the responsible person, in so far as they can be determined;
- (e) the level of cooperation of the responsible person with the competent authority;
- (f) previous breaches by the responsible legal or natural person.

Additional factors may be taken into account by competent authorities, where such factors are specified in national law.

Article 30c

Publication of sanctions and measures

1. Competent authorities shall publish on their official website at least any administrative sanction imposed for breach of the provisions of this Directive or of Regulation (EU) No 537/2014 in respect of which all rights of appeal have been exhausted or have expired, as soon as reasonably practicable immediately after the person sanctioned has been informed of that decision, including information concerning the type and nature of the breach and the identity of the natural or legal person on whom the sanction has been imposed.

Where Member States permit publication of sanctions which are subject to appeal, competent authorities shall, as soon as reasonably practicable, also publish on their official website information concerning the status and outcome of any appeal.

2. Competent authorities shall publish the sanctions imposed on an anonymous basis, and in a manner which is in conformity with national law, in any of the following circumstances:

- (a) where, in the event that the sanction is imposed on a natural person, publication of personal data is shown to be disproportionate by an obligatory prior assessment of the proportionality of such publication;
- (b) where publication would jeopardise the stability of financial markets or an ongoing criminal investigation;
- (c) where publication would cause disproportionate damage to the institutions or individuals involved.

3. Competent authorities shall ensure that any publication in accordance with paragraph 1 is of proportionate duration and that it remains on their official website for a minimum period of five years after all rights of appeal have been exhausted or have expired.

The publication of sanctions and measures and of any public statement shall respect fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, in particular the right to respect for private and family life and the right to the protection of personal data. Member States may decide that such publication or any public statement is not to contain personal data within the meaning of point (a) of Article 2 of Directive 95/46/EC.

Article 30d

Appeal

Member States shall ensure that decisions taken by the competent authority in accordance with this Directive and Regulation (EU) No 537/2014 are subject to a right of appeal.

Article 30e

Reporting of breaches

1. Member States shall ensure that effective mechanisms are established to encourage reporting of breaches of this Directive or of Regulation (EU) No 537/2014 to the competent authorities.
2. The mechanisms referred to in paragraph 1 shall include at least:
 - (a) specific procedures for the receipt of reports of breaches and their follow-up;
 - (b) protection of personal data concerning both the person who reports the suspected or actual breach and the person who is suspected of committing, or who has allegedly committed that breach, in compliance with the principles laid down in Directive 95/46/EC;
 - (c) appropriate procedures to ensure the right of the accused person to a defence and to be heard before the adoption of a decision concerning him or her, and the right to seek an effective remedy before a tribunal against any decision or measure concerning him or her.
3. Member States shall ensure that audit firms establish appropriate procedures for their employees to report potential or actual breaches of this Directive or of Regulation (EU) No 537/2014 internally through a specific channel.

Article 30f

Exchange of information

1. Competent authorities shall provide the CEAOB annually with aggregated information regarding all administrative measures and all sanctions imposed in accordance with this chapter. The CEAOB shall publish that information in an annual report.
2. Competent authorities shall immediately communicate to the CEAOB all temporary prohibitions referred to in points c) and e) of Article 30a(1).'

26. Article 32 is amended as follows:

- (a) paragraph 1 is replaced by the following:

'1. Member States shall organise an effective system of public oversight for statutory auditors and audit firms based on the principles set out in paragraphs 2 to 7, and shall designate a competent authority responsible for such oversight.'

- (b) paragraph 3 is replaced by the following:

'3. The competent authority shall be governed by non-practitioners who are knowledgeable in the areas relevant to statutory audit. They shall be selected in accordance with an independent and transparent nomination procedure.'

The competent authority may engage practitioners to carry out specific tasks and may also be assisted by experts when this is essential for the proper fulfilment of its tasks. In such instances, both the practitioners and the experts shall not be involved in any decision-making of the competent authority.;

(c) paragraph 4 is replaced by the following:

‘4. The competent authority shall have the ultimate responsibility for the oversight of:

- (a) the approval and registration of statutory auditors and audit firms;
- (b) the adoption of standards on professional ethics, internal quality control of audit firms and auditing, except where those standards are adopted or approved by other Member State authorities;
- (c) continuing education;
- (d) quality assurance systems;
- (e) investigative and administrative disciplinary systems.’;

(d) the following paragraphs are inserted:

‘4a. Member States shall designate one or more competent authorities to carry out the tasks provided for in this Directive. Member States shall designate only one competent authority bearing the ultimate responsibility for the tasks referred in this Article except for the purpose of the statutory audit of cooperatives, savings banks or similar entities as referred to in Article 45 of Directive 86/635/EEC, or a subsidiary or legal successor of a cooperative, savings bank or similar entity as referred to in Article 45 of Directive 86/635/EEC.

Member States shall inform the Commission of their designation.

The competent authorities shall be organised in such a manner that conflicts of interests are avoided.

4b. Member States may delegate or allow the competent authority to delegate any of its tasks to other authorities or bodies designated or otherwise authorised by law to carry out such tasks.

The delegation shall specify the delegated tasks and the conditions under which they are to be carried out. The authorities or bodies shall be organised in such a manner that conflicts of interest are avoided.

Where the competent authority delegates tasks to other authorities or bodies, it shall be able to reclaim the delegated competences on a case-by-case basis.’;

(e) paragraphs 5 to 7 are replaced by the following:

‘5. The competent authority shall have the right, where necessary, to initiate and conduct investigations in relation to statutory auditors and audit firms and the right to take appropriate action.

Where a competent authority engages experts to carry out specific assignments, it shall ensure that there are no conflicts of interest between those experts and the statutory auditor or the audit firm in question. Such experts shall comply with the same requirements as those provided for in point (a) of Article 29(2).

The competent authority shall be given the powers necessary to enable it to carry out its tasks and responsibilities under this Directive.

6. The competent authority shall be transparent. This shall include the publication of annual work programmes and activity reports.

7. The system of public oversight shall be adequately funded and shall have adequate resources to initiate and conduct investigations, as referred to in paragraph 5. The funding of the public oversight system shall be secure and free from any undue influence by statutory auditors or audit firms.’

27. Article 34 is amended as follows:

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

‘Without prejudice to the first subparagraph, audit firms approved in one Member State that perform audit services in another Member State pursuant to Article 3a shall be subject to quality assurance review in the home Member State and oversight in the host Member State of any audit carried out there.’

(b) paragraphs 2 and 3 are replaced by the following:

‘2. In the case of a statutory audit of consolidated financial statements, the Member State requiring that statutory audit may not impose additional requirements in relation to the statutory audit concerning registration, quality assurance review, auditing standards, professional ethics and independence on a statutory auditor or an audit firm carrying out a statutory audit of a subsidiary established in another Member State.

3. In the case of a company whose securities are traded on a regulated market in a Member State other than that in which that company has its registered office, the Member State in which the securities are traded may not impose any additional requirements in relation to the statutory audit concerning registration, quality assurance review, auditing standards, professional ethics and independence on a statutory auditor or an audit firm carrying out the statutory audit of the annual or consolidated financial statements of that company.’;

(c) the following paragraph is added:

‘4. Where a statutory auditor or an audit firm is registered in any Member State as a consequence of approval in accordance with Article 3 or Article 44 and that statutory auditor or audit firm provides audit reports concerning annual financial statements or consolidated financial statements as referred to in Article 45(1), the Member State in which the statutory auditor or the audit firm is registered shall subject that statutory auditor or audit firm to its systems of oversight, its quality assurance systems and its systems of investigation and sanctions.’

28. Article 35 is deleted.

29. Article 36 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The competent authorities of Member States responsible for approval, registration, quality assurance, inspection and discipline, the competent authorities designated in accordance with Article 20 of Regulation (EU) No 537/2014 and the relevant European Supervisory Authorities shall cooperate with each other whenever necessary for the purpose of carrying out their respective responsibilities and tasks under this Directive and Regulation (EU) No 537/2014. The competent authorities in a Member State shall render assistance to competent authorities in other Member States and to the relevant European Supervisory Authorities. In particular, competent authorities shall exchange information and cooperate in investigations relating to the carrying-out of statutory audits.’;

(b) paragraph 3 is replaced by the following:

‘3. Paragraph 2 shall not prevent competent authorities from exchanging confidential information. Information thus exchanged shall be covered by the obligation of professional secrecy, to which persons employed or formerly employed by competent authorities are subject. The obligation of professional secrecy shall also apply to any other person to whom the competent authorities have delegated tasks in relation to the purposes set out in this Directive.’;

(c) paragraph 4 is amended as follows:

(i) in the third subparagraph, point (b) is replaced by the following:

‘(b) judicial proceedings have already been initiated in respect of the same actions and against the same persons before the authorities of the requested Member State; or’;

(ii) in the third subparagraph, point (c) is replaced by the following:

‘(c) final judgment has already been passed in respect of the same actions and on the same persons by the competent authorities of the requested Member State.’

(iii) the fourth subparagraph is replaced by the following:

‘Without prejudice to the obligations to which they are subject in judicial proceedings, competent authorities or European Supervisory Authorities which receive information pursuant to paragraph 1 may use it only for the exercise of their functions within the scope of this Directive or Regulation (EU) No 537/2014 and in the context of administrative or judicial proceedings specifically related to the exercise of those functions.’;

(d) the following paragraph is added:

‘4a. Member States may allow competent authorities to transmit to the competent authorities responsible for supervising public-interest entities, to central banks, to the European System of Central Banks and to the European Central Bank, in their capacity as monetary authorities, and to the European Systemic Risk Board, confidential information intended for the performance of their tasks. Such authorities or bodies shall not be prevented from communicating to the competent authorities information that the competent authorities may need in order to carry out their duties under Regulation (EU) No 537/2014.’;

(e) in the fourth subparagraph of paragraph 6, point (a) is replaced by the following:

‘(a) such an investigation might adversely affect the sovereignty, security or public order of the requested Member State or breach national security rules; or’;

(f) paragraph 7 is deleted.

30. In Article 37, the following paragraph is added:

‘3. Any contractual clause restricting the choice by the general meeting of shareholders or members of the audited entity pursuant to paragraph 1 to certain categories or lists of statutory auditors or audit firms as regards the appointment of a particular statutory auditor or audit firm to carry out the statutory audit of that entity shall be prohibited. Any such existing clauses shall be null and void.’

31. In Article 38, the following paragraph is added:

‘3. In the case of a statutory audit of a public-interest entity, Member States shall ensure that it is permissible for

(a) shareholders representing 5 % or more of the voting rights or of the share capital;

(b) the other bodies of the audited entities when defined by national legislation; or

(c) the competent authorities referred to in Article 32 of this Directive or designated in accordance with Article 20(1) of Regulation (EU) No 537/2014 or, when provided for by national law, with Article 20(2) of that Regulation,

to bring a claim before a national court for the dismissal of the statutory auditor(s) or the audit firm(s) where there are proper grounds for so doing.’

32. Chapter X is replaced by the following:

‘CHAPTER X

AUDIT COMMITTEE

Article 39

Audit committee

1. Member States shall ensure that each public-interest entity has an audit committee. The audit committee shall be either a stand-alone committee or a committee of the administrative body or supervisory body of the audited entity. It shall be composed of non-executive members of the administrative body and/or members of the supervisory body of the audited entity and/or members appointed by the general meeting of shareholders of the audited entity or, for entities without shareholders, by an equivalent body.

At least one member of the audit committee shall have competence in accounting and/or auditing.

The committee members as a whole shall have competence relevant to the sector in which the audited entity is operating.

A majority of the members of the audit committee shall be independent of the audited entity. The chairman of the audit committee shall be appointed by its members or by the supervisory body of the audited entity, and shall be independent of the audited entity. Member States may require the chairman of the audit committee to be elected annually by the general meeting of shareholders of the audited entity.

2. By way of derogation from paragraph 1, Member States may decide that in the case of public-interest entities which meet the criteria set out in points (f) and (t) of Article 2(1) of Directive 2003/71/EC of the European Parliament and of the Council (*), the functions assigned to the audit committee may be performed by the administrative or supervisory body as a whole, provided that where the chairman of such a body is an executive member, he or she shall not act as chairman whilst such body is performing the functions of the audit committee.

Where an audit committee forms part of the administrative body or of the supervisory body of the audited entity in accordance with paragraph 1, Member States may permit or require the administrative body or the supervisory body, as appropriate, to perform the functions of the audit committee for the purpose of the obligations set out in this Directive and in Regulation (EU) No 537/2014.

3. By way of derogation from paragraph 1, Member States may decide that the following public-interest entities are not required to have an audit committee:

- (a) any public-interest entity which is a subsidiary undertaking within the meaning of point 10 of Article 2 of Directive 2013/34/EU if that entity fulfils the requirements set out in paragraphs 1, 2 and 5 of this Article, Article 11(1), Article 11(2) and Article 16(5) of Regulation (EU) No 537/2014 at group level;
- (b) any public-interest entity which is an UCITS as defined in Article 1(2) of Directive 2009/65/EC of the European Parliament and of the Council (**), or an alternative investment fund (AIF) as defined in Article 4(1)(a) of Directive 2011/61/EU of the European Parliament and of the Council (***);
- (c) any public-interest entity the sole business of which is to act as an issuer of asset backed securities as defined in point 5 of Article 2 of Commission Regulation (EC) No 809/2004 (****);
- (d) any credit institution within the meaning of point 1 of Article 3(1) of Directive 2013/36/EU whose shares are not admitted to trading on a regulated market of any Member State within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC and which has, in a continuous or repeated manner, issued only debt securities admitted to trading in a regulated market, provided that the total nominal amount of all such debt securities remains below EUR 100 000 000 and that it has not published a prospectus under Directive 2003/71/EC.

The public-interest entities referred to in point (c) shall explain to the public the reasons why they consider that it is not appropriate for them to have either an audit committee or an administrative or supervisory body entrusted to carry out the functions of an audit committee.

4. By way of derogation from paragraph 1, Member States may require or allow a public-interest entity not to have an audit committee provided that it has a body or bodies performing equivalent functions to an audit committee, established and functioning in accordance with provisions in place in the Member State in which the entity to be audited is registered. In such a case the entity shall disclose which body carries out those functions and how that body is composed.

5. Where all members of the audit committee are members of the administrative or supervisory body of the audited entity, the Member State may provide that the audit committee is to be exempt from the independence requirements laid down in the fourth subparagraph of paragraph 1.

6. Without prejudice to the responsibility of the members of the administrative, management or supervisory bodies, or of other members who are appointed by the general meeting of shareholders of the audited entity, the audit committee shall, *inter alia*:

- (a) inform the administrative or supervisory body of the audited entity of the outcome of the statutory audit and explain how the statutory audit contributed to the integrity of financial reporting and what the role of the audit committee was in that process;
- (b) monitor the financial reporting process and submit recommendations or proposals to ensure its integrity;
- (c) monitor the effectiveness of the undertaking's internal quality control and risk management systems and, where applicable, its internal audit, regarding the financial reporting of the audited entity, without breaching its independence;
- (d) monitor the statutory audit of the annual and consolidated financial statements, in particular, its performance, taking into account any findings and conclusions by the competent authority pursuant to Article 26(6) of Regulation (EU) No 537/2014;
- (e) review and monitor the independence of the statutory auditors or the audit firms in accordance with Articles 22, 22a, 22b, 24a and 24b of this Directive and Article 6 of Regulation (EU) No 537/2014, and in particular the appropriateness of the provision of non-audit services to the audited entity in accordance with Article 5 of that Regulation;
- (f) be responsible for the procedure for the selection of statutory auditor(s) or audit firm(s) and recommend the statutory auditor(s) or the audit firm(s) to be appointed in accordance with Article 16 of Regulation (EU) No 537/2014 except when Article 16(8) of Regulation (EU) No 537/2014 is applied.

(*) 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 and amending Directive 2001/34/EC (OJ L 345, 31.12.2003, p. 64).

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

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

(****) Commission Regulation (EC) No 809/2004 of 29 April 2004 implementing Directive 2003/71/EC of the European Parliament and of the Council as regards information contained in prospectuses as well as the format, incorporation by reference and publication of such prospectuses and dissemination of advertisements (OJ L 149, 30.4.2004, p. 1).

33. Article 45 is amended as follows:

- (a) paragraph 1 is replaced by the following:

'1. The competent authorities of a Member State shall, in accordance with Articles 15, 16 and 17, register every third-country auditor and audit entity, where that third-country auditor or audit entity provides an audit report concerning the annual or consolidated financial statements of an undertaking incorporated outside the Union whose transferable securities are admitted to trading on a regulated market of that Member State within the meaning of point 14 of Article 4(1) of Directive 2004/39/EC, except when the undertaking in question is an issuer exclusively of outstanding debt securities for which one of the following applies:

- (a) they have been admitted to trading on a regulated market in a Member State within the meaning of point (c) of Article 2(1) of Directive 2004/109/EC of the European Parliament and of the Council (*) prior to 31 December 2010 and the denomination per unit of which is, at the date of issue, at least EUR 50 000 or, in the case of debt securities denominated in another currency, equivalent, at the date of issue, to at least EUR 50 000;

- (b) they are admitted to trading on a regulated market in a Member State within the meaning of point (c) of Article 2(1) of Directive 2004/109/EC from 31 December 2010 and the denomination per unit of which is, at the date of issue, at least EUR 100 000 or, in case of debt securities denominated in another currency, equivalent, at the date of issue, to at least EUR 100 000.

(*) 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 and amending Directive 2001/34/EC (OJ L 390, 31.12.2004, p. 38).;

- (b) paragraph 5 is amended as follows:

(i) point (a) is deleted;

(ii) point (d) is replaced by the following:

‘(d) the audits of the annual or consolidated financial statements referred to in paragraph 1 are carried out in accordance with international auditing standards as referred to in Article 26, as well as the requirements laid down in Articles 22, 22b and 25, or with equivalent standards and requirements;’

(iii) point (e) is replaced by the following:

‘(e) it publishes on its website an annual transparency report which includes the information referred to in Article 13 of Regulation (EU) No 537/2014 or it complies with equivalent disclosure requirements.’;

- (c) the following paragraph is inserted:

‘5a. A Member State may register a third-country auditor only if he or she meets the requirements set out in points (c), (d) and (e) of paragraph 5 of this Article.’;

- (d) paragraph 6 is replaced by the following:

‘6. In order to ensure uniform conditions of application of point (d) of paragraph 5 of this Article, the Commission shall be empowered to decide upon the equivalence referred to therein by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2). Member States may assess the equivalence referred to in point (d) of paragraph 5 of this Article as long as the Commission has not taken any such decision.

The Commission shall be empowered to adopt delegated acts in accordance with Article 48a for the purpose of establishing the general equivalence criteria to be used in assessing whether the audits of the financial statements referred to in paragraph 1 of this Article are carried out in accordance with international auditing standards as referred to in Article 26 and the requirements laid down in Articles 22, 24 and 25. Such criteria, which are applicable to all third countries, shall be used by Member States when assessing equivalence at national level.’

34. In Article 46, paragraph 2 is replaced by the following:

‘2. In order to ensure uniform conditions for the application of paragraph 1 of this Article, the Commission shall be empowered to decide upon the equivalence referred to therein by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2). Once the Commission has recognised the equivalence referred to in paragraph 1 of this Article, Member States may decide to rely on such equivalence partially or entirely and thus to disapply or modify the requirements in Article 45(1) and (3) partially or entirely. Member States may assess the equivalence referred to in paragraph 1 of this Article or rely on the assessments carried out by other Member States as long as the Commission has not taken any such decision. If the Commission decides that the requirement of equivalence referred to in paragraph 1 of this Article is not complied with, it may allow the third-country auditors and third-country audit entities concerned to continue their audit activities in accordance with the requirements of the relevant Member State during an appropriate transitional period.

The Commission shall be empowered to adopt delegated acts in accordance with Article 48a for the purpose of establishing the general equivalence criteria, based on the requirements laid down in Articles 29, 30 and 32, which are to be used in assessing whether the public oversight, quality assurance, investigation and sanctions systems of a third country are equivalent to those of the Union. Such general criteria shall be used by Member States when assessing equivalence at national level in the absence of a Commission decision in respect of the third country concerned.'

35. Article 47 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) the introductory words are replaced by the following:

'1. Member States may allow the transfer to the competent authorities of a third country of audit working papers or other documents held by statutory auditors or audit firms approved by them, and of inspection or investigation reports relating to the audits in question, provided that:'

(ii) point (a) is replaced by the following:

'(a) those audit working papers or other documents relate to audits of companies which have issued securities in that third country or which form part of a group issuing statutory consolidated financial statements in that third country;'

(b) in paragraph 2, the following point is inserted:

'(ba) the protection of the commercial interests of the audited entity, including its industrial and intellectual property, is not undermined;'

(c) in paragraph 2, the second indent of point (d) shall be replaced by the following:

'— where judicial proceedings have already been initiated in respect of the same actions and against the same persons before the authorities of the requested Member State, or

— where final judgment has already been passed in respect of the same actions and on the same statutory auditors or audit firms by the competent authorities of the requested Member State;'

(d) paragraph 3 is replaced by the following:

'3. In order to facilitate cooperation, the Commission shall be empowered to decide upon the adequacy referred to in point (c) of paragraph 1 of this Article by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2). Member States shall take the measures necessary to comply with the Commission's decision.

The Commission shall be empowered to adopt delegated acts in accordance with Article 48a for the purpose of establishing the general adequacy criteria in accordance with which the Commission is to assess whether the competent authorities of third countries may be recognised as adequate to cooperate with the competent authorities of Member States on the exchange of audit working papers or other documents held by statutory auditors and audit firms. The general adequacy criteria shall be based on the requirements of Article 36 or essentially equivalent functional results relating to a direct exchange of audit working papers or other documents held by statutory auditors or audit firms;'

(e) paragraph 5 is deleted.

36. In Article 48, paragraphs 1 and 2 are replaced by the following:

'1. The Commission shall be assisted by a committee (hereinafter referred to as "the Committee"). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*).

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

(*) 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 power (OJ L 55, 28.2.2011, p. 13).'

37. The following Article is inserted:

'Article 48a

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Articles 26(3), 45(6), 46(2) and 47(3) shall be conferred on the Commission for a period of five years from 16 June 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 26(3), 45(6), 46(2) and 47(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Articles 26(3), 45(6), 46(2) and 47(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of four months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'

38. Article 49 is deleted.

Article 2

Transposition

1. By 17 June 2016 Member States shall adopt and publish the measures necessary to comply with this Directive. They shall immediately inform the Commission thereof. Member States shall apply those measures from 17 June 2016.

2. When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

3. Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

*Article 3***Entry into force**

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

*Article 4***Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 16 April 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

DECISIONS

**DECISION No 541/2014/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
establishing a Framework for Space Surveillance and Tracking Support**

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 189(2) thereof,

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) In its Communication of 4 April 2011 entitled 'Towards a space strategy for the European Union that benefits its citizens', the Commission underlined that the shared competence in the field of space conferred upon the Union by the Treaty on the Functioning of the European Union (TFEU) goes hand in hand with a reinforced partnership with the Member States. The Commission also emphasised that all new action must be based on existing resources and on the joint identification of where new resources are needed.
- (2) In its Resolution of 26 September 2008 entitled 'Taking forward the European Space Policy' ⁽³⁾, the Council recalled that space assets have become indispensable for our economy and that their security must be ensured. It underlined the 'need for Europe [...] to develop a European capability for the monitoring and surveillance of its space infrastructure and space debris, initially based on existing national and European assets, taking benefit of relationships which may be established with other partner nations and their capabilities'.
- (3) In its Resolution of 25 November 2010 entitled 'Global challenges: taking full benefit of European space systems', the Council recognised the need for a future space situational awareness (SSA) capability as an activity at European level to develop and exploit existing national and European civil and military assets, and invited the Commission and the Council to propose a governance scheme and data policy that will allow Member States to contribute with their relevant national capabilities in accordance with applicable security requirements and regulations. It further invited 'all European institutional actors to explore appropriate measures' which would build on defined civil and military user requirements, make use of relevant assets in accordance with applicable security requirements, and exploit the developments from the SSA preparatory programme of the European Space Agency (ESA).
- (4) The Council conclusions of 31 May 2011 on the Communication of the Commission 'Towards a space strategy for the European Union that benefits its citizens' and the Council Resolution of 6 December 2011 entitled 'Orientations concerning added value and benefits of space for the security of European citizens' ⁽⁴⁾ reiterated the need for an effective SSA capability as an activity at European level, and called on the Union to make 'the widest

⁽¹⁾ OJ C 327, 12.11.2013, p. 38.

⁽²⁾ Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.

⁽³⁾ OJ C 268, 23.10.2008, p. 1.

⁽⁴⁾ OJ C 377, 23.12.2011, p. 1.

possible use of assets, competences and skills that are already existing or being developed in Member States, at European level and as appropriate, internationally'. Recognising the dual use nature of such a system and taking account its particular security dimension, the Council called upon the Commission and European External Action Service (EEAS), in close cooperation with ESA and Member States, which own such assets and have capacities, and in consultation with all actors involved, to come forward with proposals to fully exploit and build on those assets and capacities in order to develop a SSA capability as an activity at European level, and in that context, to define an appropriate governance and data policy taking care of the high sensitivity of SSA data.

- (5) SSA is generally understood as covering three main areas, namely Space Surveillance and Tracking (SST), Space Weather Monitoring and Forecasting and Near-Earth Objects. Activities in these areas aim to protect infrastructures in space and from space. This Decision, which covers SST, should foster synergies across these areas.
- (6) With a view to reducing risks of collision, the Union would also seek synergies with initiatives of active removal and passivation measures of space debris, such as the one developed by ESA.
- (7) Space debris has become a serious threat to the security, safety and sustainability of space activities. An SST support framework should therefore be established with the aim of supporting the setting up and operation of services consisting of monitoring and surveying space objects with a view to preventing damage to spacecraft resulting from collisions and the proliferation of space debris, and with the aim of predicting trajectories and re-entry paths, in order to provide the best information to governmental and civil protection services in the event of uncontrolled re-entries of entire spacecraft or space debris thereof into the Earth's atmosphere.
- (8) The SST support framework should contribute to ensuring the long-term availability of European and national space infrastructure facilities and services which are essential for the safety and security of the economies, societies and citizens in Europe.
- (9) The provision of SST services will benefit all public and private operators of space-based infrastructures, including the Union, in view of the Union's responsibilities for the Union space programmes, in particular the European satellite navigation programmes Galileo and EGNOS established by Regulation (EU) No 1285/2013 of the European Parliament and of the Council ⁽¹⁾, as well as the Copernicus Programme established by Regulation (EU) No 377/2014 of the European Parliament and of the Council ⁽²⁾. Early warnings of uncontrolled re-entry and estimation of timeframe and area of impact will also benefit national public authorities concerned with civil protection. Moreover those services might also be of interest to other users, such as private insurers to estimate potential liabilities resulting from collision during the life of a satellite. In addition, a freely available and re-usable public information service on orbital elements of space objects orbiting the Earth should be envisaged in the long term.
- (10) The SST services should be complementary to research activities related to the protection of space-based infrastructure carried out under Horizon 2020 established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council ⁽³⁾, the Union's flagship space programmes Copernicus and Galileo, the Digital Agenda initiative, as referred to in the Commission Communication of 26 August 2010 entitled 'A Digital Agenda for Europe', other telecommunication infrastructures, which aid the realisation of the information society, security-related initiatives, as well as to ESA activities.
- (11) The SST support framework should contribute to ensuring the peaceful use and exploration of outer space.
- (12) The SST support framework should have regard to cooperation with international partners, in particular the United States of America, international organisations and other third parties, particularly to avoid collisions in space and to prevent the proliferation of space debris. In addition, it should be complementary to existing mitigation measures such as the United Nations guidelines for space debris mitigation or other initiatives, to ensure the safety, security and sustainability of outer space activities. It should also be consistent with the Union proposal for an international Code of Conduct on outer space activities.

⁽¹⁾ Regulation (EU) No 1285/2013 of the European Parliament and of the Council of 11 December 2013 on the implementation and exploitation of European satellite navigation systems and repealing Council Regulation (EC) No 876/2002 and Regulation (EC) No 683/2008 of the European Parliament and of the Council (OJ L 347, 20.12.2013, p. 1).

⁽²⁾ Regulation (EU) No 377/2014 of the European Parliament and of the Council of 3 April 2014 establishing the Copernicus Programme and repealing Regulation (EU) No 911/2010 (OJ L 122, 24.4.2014, p. 44).

⁽³⁾ Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).

- (13) The SST support framework should consist in networking and in using national SST assets to provide SST services. Once this has been achieved, the development of new sensors or the upgrading of existing sensors operated by Member States should be encouraged.
- (14) The Commission and the SST consortium established under this Decision, in close cooperation with ESA and other stakeholders, should continue to take the lead in technical SST dialogues with strategic partners, in accordance with their respective competences.
- (15) Civil-military SSA user requirements were defined in the endorsed Commission staff working paper 'European space situational awareness high-level civil-military user requirements'. The provision of SST services should be driven by civilian user requirements. Purely military purposes should not be addressed by this Decision. The Commission should ensure a mechanism for the regular review and update of user requirements as appropriate, involving representatives of the user community. To that end, it should continue the necessary dialogue with relevant actors such as the European Defence Agency and ESA.
- (16) The operation of SST services should be based on a partnership between the Union and the Member States and use existing as well as future national expertise and assets, including those developed through ESA. Member States should retain ownership and control over their assets and should remain responsible for their operations, maintenance and renewal. The SST support framework should not provide financial support for the development of new SST sensors. If a need for new sensors arises in order to meet user requirements, that need could be addressed either nationally or through a European research and development programme, where appropriate. The Commission and the Member States should promote and facilitate participation by the greatest number of Member States in the SST support framework, subject to compliance with participation criteria.
- (17) The European Union Satellite Centre (SATCEN), an agency of the Union established by Council Joint Action 2001/555/CFSP ⁽¹⁾ which provides geospatial imagery information services and products with various levels of classification to civil and military users, could contribute to the provision of SST services. Its expertise in handling classified information in a secure environment and its tight institutional links with the Member States is an asset facilitating the handling and delivery of SST services. A pre-condition for the SATCEN role in the SST support framework is the amendment of that Joint Action which does currently not provide for SATCEN action in the field of SST. The Commission should, where appropriate, cooperate with the EEAS, given the latter's role in supporting the High Representative of the Union for Foreign Affairs and Security Policy in giving operational direction to SATCEN.
- (18) Precise information on the nature, specifications and location of certain space objects may affect the security of the Union or its Member States and third countries. The Member States and, where appropriate, through the Security Committee of the Council (Security Committee) should take into account adequate security considerations and, in the establishment and operation of the network of relevant capabilities, including SST sensors, the capacity to process and analyse SST data and the provision of SST services. It is therefore necessary to lay down in this Decision general provisions on the use and secure exchange of SST information between the Member States, the recipients of SST services and, where relevant, the SATCEN. Furthermore, the Commission, the EEAS and the Member States should define the coordination mechanisms needed to address matters related to the security of the SST support framework.
- (19) Participating Member States should be responsible for the negotiation and implementation of the provisions on the use of SST data and on the use and exchange of SST information. The provisions on the use of SST data and on the use and exchange of SST information set out in this Decision and in the agreement between the participating Member States and, where appropriate, the SATCEN should take into account the endorsed recommendations on SST data security.
- (20) The potential sensitivity of SST data calls for cooperation based on efficiency and confidence, including in the way in which SST data are processed and analysed. The potential use of open source software allowing the secure access of authorised SST data contributors to the source code for operational modifications and improvements should contribute to that objective.

⁽¹⁾ Council Joint Action 2001/555/CFSP of 20 July 2001 on the establishment of a European Union Satellite Centre (OJ L 200, 25.7.2001, p. 5).

- (21) The Security Committee recommended the creation of a risk management structure to ensure that data security issues are duly taken into account in the implementation of the SST support framework. For that purpose, the appropriate risk management structures and procedures should be established by the participating Member States and, where relevant, the SATCEN, having regard to the recommendations of the Security Committee.
- (22) In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (23) Since the objectives of this Decision, namely to support actions aimed at the establishment and operation of the network of sensors, the establishment of the capacity to process and analyse SST data, and the establishment and operation of SST services, cannot be sufficiently achieved by the Member States acting alone, as the provision of such services by a consortium of participating Member States would benefit the Union, notably in its role as major owner of space assets, but can rather, by reason of the scale of the Decision, 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 of the European Union. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.
- (24) The objectives of this Decision are similar to the objectives of the programmes established by: Regulation (EU) No 1285/2013, in its Articles 1, 3 (c) and (d) and 4; Council Decision 2013/743/EU ⁽²⁾, in its Article 2(2)(b) and (c), in its Annex I, Part II, point 1.6.2 (d) and in its Annex I, Part III, points 7.5 and 7.8; Regulation (EU) No 377/2014, in its Article 8(2)(b), which allocates an amount up to EUR 26,5 million in current prices. The overall financial effort for the implementation of the objectives of the SST support framework, notably the networking of existing assets, is estimated to be EUR 70 million. Taking into account the similarity of the objectives of this Decision and those of the above-mentioned programmes, the actions established by this Decision might be financed by those programmes, in full compatibility with their basic act.
- (25) Securing an acceptable level of European autonomy in SST activities could require the adoption of a basic act within the meaning of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ⁽³⁾ for SST. Such possibility should be examined in the context of the mid-term review of the current Multiannual Financial Framework.
- (26) Recognising the sensitive nature of SSA, the operation of sensors and the processing of data leading to the provision of SST services should remain with the participating Member States. The national SST assets will remain under the authority of the Member States responsible for their control and operation.

HAVE ADOPTED THIS DECISION:

Article 1

Establishment of the framework

This Decision establishes a space surveillance and tracking (SST) support framework.

Article 2

Definitions

For the purpose of this Decision, the following definitions apply:

- (1) 'Space object' means any man-made object in outer space;
- (2) 'Spacecraft' means any space object serving a specific purpose, including active artificial satellites and launcher upper stages;

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽²⁾ Council Decision 2013/743/EU of 3 December 2013 establishing the specific programme implementing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC (OJ L 347, 20.12.2013, p. 965).

⁽³⁾ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

- (3) 'Space debris' means any space object including spacecraft or fragments and elements thereof in Earth's orbit or re-entering Earth's atmosphere, that are non-functional or no longer serve any specific purpose, including parts of rockets or artificial satellites, or inactive artificial satellites;
- (4) 'SST sensor' means a device or a combination of devices, such as ground-based or space-based radars and telescopes, that is able to measure physical parameters related to space objects, such as size, location and speed;
- (5) 'SST data' means physical parameters of space objects acquired by SST sensors or orbital parameters of space objects derived from SST sensors' observations;
- (6) 'SST information' means processed SST data which is readily meaningful to the recipient.

Article 3

Objectives of the SST support framework

1. The general objective of the SST support framework is to contribute to ensuring the long-term availability of European and national space infrastructure, facilities and services which are essential for the safety and security of the economies, societies and citizens in Europe.
2. The specific objectives of the SST support framework are:
 - (a) assessing and reducing the risks to in-orbit operations of European spacecraft relating to collisions and enabling spacecraft operators to plan and carry out mitigation measures more efficiently;
 - (b) reducing the risks relating to the launch of European spacecraft;
 - (c) surveying uncontrolled re-entries of spacecraft or space debris into the Earth's atmosphere and providing more accurate and efficient early warnings with the aim of reducing the potential risks to the safety of Union citizens and mitigating potential damage to terrestrial infrastructure;
 - (d) seeking to prevent the proliferation of space debris.

Article 4

Actions supported by the SST support framework

1. To attain the objectives laid down in Article 3, the SST support framework shall support the following actions which aim to establish a SST capability at European level and with an appropriate level of European autonomy:
 - (a) the establishment and operation of a sensor function consisting of a network of Member State ground-based and/or space-based sensors, including national sensors developed through ESA, to survey and track space objects and to produce a database thereof;
 - (b) the establishment and operation of a processing function to process and analyse the SST data at national level to produce SST information and services for transmission to the SST service provision function;
 - (c) the setting up of a function to provide SST services as defined in Article 5(1) to the entities referred to in Article 5(2).
2. The SST support framework shall not cover the development of new SST sensors.

Article 5

SST services

1. The SST services referred to in Article 4 shall be of a civilian nature. They shall comprise the following services:
 - (a) the risk assessment of collision between spacecraft or between spacecraft and space debris and the generation of collision avoidance alerts during the launch, early orbit, in-orbit operation and disposal phases of spacecraft missions;
 - (b) the detection and characterisation of in-orbit fragmentations, break-ups or collisions;
 - (c) the risk assessment of the uncontrolled re-entry of space objects and space debris into the Earth's atmosphere and the generation of related information, including the estimation of the timeframe and likely location of possible impact.

2. SST services shall be provided to:
 - (a) all Member States;
 - (b) the Council;
 - (c) the Commission;
 - (d) the EEAS;
 - (e) public and private spacecraft owners and operators;
 - (f) public authorities concerned with civil protection.

SST services shall be provided in compliance with the provisions on the use and exchange of SST data and information set out in Article 9.

3. Participating Member States, the Commission and, where relevant, the SATCEN, shall not be held liable for:
 - (a) any damage resulting from the lack of or interruption in the provision of SST services;
 - (b) any delay in the provision of SST services;
 - (c) any inaccuracy of the information provided through the SST services; or
 - (d) any action undertaken in response to the provision of SST services.

Article 6

Role of the Commission

1. The Commission shall:
 - (a) manage the SST support framework and ensure its implementation;
 - (b) take the measures necessary to identify, control, mitigate and monitor risks related to the SST support framework;
 - (c) ensure the update of SST user requirements as appropriate;
 - (d) define general guidelines for the governance of the SST support framework, particularly to facilitate the establishment and operation of the consortium referred to in Article 7(3);
 - (e) facilitate the broadest possible participation of Member States, whenever appropriate, in accordance with Article 7.
2. The Commission shall adopt implementing acts establishing a coordination plan and relevant technical measures for the SST support framework activities. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 12(2).
3. The Commission shall provide to the European Parliament and to the Council, in a timely manner, all relevant information on the implementation of the SST support framework, in particular to provide transparency and clarity regarding:
 - (a) the indicative efforts and the different Union sources of funding;
 - (b) participation in the SST support framework and the actions supported thereby;
 - (c) the evolution of the networking of Member State SST assets and of SST service provision;
 - (d) the exchange and use of SST information.

Article 7

Participation of Member States

1. A Member State wishing to participate in the implementation of the actions referred to in Article 4 shall submit an application to the Commission demonstrating compliance with the following criteria:
 - (a) ownership of or access to:
 - (i) adequate SST sensors available or under development and technical and human resources to operate them, or
 - (ii) adequate operational analysis and data processing capacities specifically designated for SST;
 - (b) establishment of an action plan for the implementation of the actions set out in Article 4 including the modalities of cooperation with other Member States.

2. The Commission shall adopt implementing acts regarding procedures for submission of applications and compliance of the Member States with the criteria set out in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 12(2).
3. All Member States which comply with the criteria referred to in paragraph 1 shall designate a national entity to represent them. The designated national entities shall constitute a consortium and shall conclude the agreement referred to in Article 10.
4. The Commission shall publish and update on its website the list of participating Member States.
5. Responsibility for the operation of sensors, the processing of data and the implementation of data policy shall lie with the participating Member States. The assets of participating Member States shall remain fully under national control.

Article 8

Role of the European Union Satellite Centre

The European Union Satellite Centre (SATCEN) may cooperate with the consortium to be established pursuant to Article 7(3). In that case, it shall conclude the necessary implementing arrangements with the participating Member States.

Article 9

SST data and SST information

The use and exchange of SST information released by the consortium and the use of SST data within the context of the SST support framework for the purposes of the implementation of the actions referred to in Article 4 shall be subject to the following rules:

- (a) unauthorised disclosure of data and information shall be prevented while allowing efficient operations and maximising the use of the generated information;
- (b) the security of SST data shall be ensured;
- (c) SST information and services shall be made available on a need-to-know basis to the recipients of the SST services defined in Article 5(2), in accordance with the instructions and security rules of the originator of the information and of the owner of the space object concerned.

Article 10

Coordination of operational activities

The designated national entities that constitute the consortium referred to in Article 7(3) shall conclude an agreement laying down the rules and mechanisms for their cooperation in the implementation of the actions referred to in Article 4. In particular, that agreement shall include provisions for:

- (a) the use and exchange of SST information taking into account the endorsed recommendations 'Space Situational Awareness data policy — recommendations on security aspects';
- (b) the establishment of a risk management structure to ensure the implementation of the provisions on the use and secure exchange of SST data and SST information;
- (c) cooperation with the SATCEN to implement the action referred to in Article 4(1)(c).

Article 11

Monitoring and evaluation

1. The Commission shall monitor the implementation of the SST support framework.
2. By 1 July 2018, the Commission shall forward a report on the implementation of the SST support framework to the European Parliament and the Council concerning the achievement of the objectives of this Decision, from the point of view of both results and impacts, the effectiveness of the use of resources and the European added value.

This report may be accompanied by proposals for amendments, where appropriate, including the possibility for a basic act within the meaning of the Regulation (EU, Euratom) No 966/2012 for SST.

Article 12

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where a reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 13

Entry into force

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 14

This Decision is addressed to the Member States.

Done at Strasbourg, 16 April 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

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