



7.2.2023

PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS

**Subject: Proposal for a regulation of the European Parliament and of the Council on
Machinery products
(COM(2021)0202 – C9-0145/2021 – 2021/0105(COD))**

The interinstitutional negotiations on the aforementioned proposal for a regulation have led to a compromise. In accordance with Rule 74(4) of the Rules of Procedure, the provisional agreement, reproduced below, is submitted as a whole to the Committee on the Internal Market and Consumer Protection for decision by way of a single vote.

2021/0105 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on machinery 

(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 Committee¹,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C [...], [...], p. [...].

Whereas:

- (1) Directive 2006/42/EC² of the European Parliament and of the Council was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for machinery in all Member States and to remove obstacles to trade in machinery between Member States.
- (2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Union economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.
- (3) Experience with the application of Directive 2006/42/EC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. It is therefore necessary to improve, simplify and adapt the provisions set out in that Directive to the needs of the market and provide clear rules in relation to the framework within which ***products within the scope of this Regulation*** may be made available on the market.
- (4) Since the rules setting out the requirements for ***products within the scope of this Regulation***, in particular the essential health and safety requirements and the conformity assessment procedures, need to be of uniform application for all operators across the Union, and not give room for divergent implementation by Member States, Directive 2006/42/EC should be replaced by a regulation.

² Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

- (5) Member States are responsible for protecting, on their territory, the health and safety of persons, in particular workers and consumers, and, where appropriate, domestic animals and property, **and, where applicable, the environment**, notably in relation to the risks arising out of the **intended use or reasonably foreseeable misuse** of machinery **or related products**. For the avoidance of doubt, domestic animals should be considered to include farm animals.
- (6) Regulation (EC) No 765/2008 of the European Parliament³ lays down rules on the accreditation of conformity assessment bodies, ■ and lays down the general principles of the CE marking. That Regulation should be applicable to **products within the scope of** this Regulation in order to ensure that those products, which are benefiting from the free movement of goods within the Union, fulfil requirements providing a high level of protection of public interests such as the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.
- (7) Regulation (EU) 2019/1020 of the European Parliament and of the Council⁴ sets out rules on market surveillance and control of products entering the Union market. **As Directive 2006/42/EC is listed in Annex I of Regulation (EU) 2019/1020**, that Regulation already applies to **products within the scope of this Regulation**. **However, Regulation (EU) 2019/1020 applies to products within the scope of this Regulation in so far as there are no specific provisions with the same objective, which regulate in a more specific manner particular aspects of market surveillance and enforcement.**

³ 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).

⁴ Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1.)

- (7a) *Article 4 of Regulation (EU) 2019/1020 lays down the tasks of economic operators regarding products subject to certain Union harmonisation legislation. It also provides that such products are to be placed on the market only if there is an economic operator established in the Union who is responsible for those tasks. That Union harmonisation legislation includes Directive 2006/42/EC. As a result, products within the scope of this Regulation are to be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in Article 4 of Regulation (EU) 2019/1020 in their respect.*
- (8) Decision No 768/2008/EC of the European Parliament and of the Council⁵ lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the rules on presumption of conformity, the rules on EU declaration of conformity, the rules on CE marking, the requirements for conformity assessment bodies, the rules on notification procedures and conformity assessment procedures and the rules on procedures to deal with machinery *or related* products **and, where applicable, with partly completed machinery**, presenting a risk should be adapted to the reference provisions laid down in that Decision.
- (9) This Regulation should cover **■** products which are new to the Union market when placed on the market, i.e. either new **■** products made by a manufacturer established in the Union or **■** products, whether new or second-hand, imported from a third country.

⁵ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

- (10) Where there is a possibility that the machinery *or related* products will be used by a consumer, that is to say, a non-professional *user*, the manufacturer should take account of the fact that the consumer does not have the same knowledge and experience with handling machinery *or related* products in the design and construction of the products. The same applies where a machinery *or related* product is normally used to provide a service to a consumer.
- (11) Recently, more advanced *machinery*, which *is* less dependent on human operators, *has* been introduced on the market. *Such machinery is* working on defined tasks and in structured environments, yet *it* can learn to perform new actions in this context and become more autonomous. Further refinements to *machinery*, already in place or to be expected, include real-time processing of information, problem solving, mobility, sensor systems, learning, adaptability, and capability of operating in unstructured environments (e.g. construction sites). The Commission Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics⁶, states that the emergence of new digital technologies, like artificial intelligence, the Internet of things and robotics, raises new challenges in terms of product safety. The report concludes that the current product safety legislation, including Directive 2006/42/EC, contains a number of gaps in this respect that need to be addressed. Thus, this Regulation should cover the safety risks stemming from new digital technologies.
- (12) In order to ensure protection of the health and safety of persons, *and, where appropriate*, domestic animals *and* property and, where applicable, the environment, this Regulation should apply to all forms of supply of *products within the scope of this Regulation*, including distance selling as referred to in Article 6 of Regulation (EU) 2019/1020.

⁶ Report from the Commission to the European parliament, the Council and the European economic and social committee on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics (COM(2020)0064).

- (13) In order to ensure legal certainty **■**, the scope of this Regulation should be set out in a clear manner and the concepts relating to its application should be defined as precisely as possible.
- (13a) *In order to ensure that the scope of this Regulation is sufficiently clear, a distinction should be made between machinery, related products and partly completed machinery. Moreover, related products should be understood as comprising interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, and removable mechanical transmission devices, which are all products within the scope of this Regulation.*
- (14) In order to avoid legislating twice the same product, it is appropriate to exclude from the scope of this Regulation weapons, including firearms that are subject to Directive (EU) 2017/853 of the European Parliament and of the Council⁷.
- (15) **■** The purpose of this Regulation is to address the risks stemming from **■** machinery function and not *from* the transport of goods, *persons or animals*. *Consequently, this Regulation should not apply to means of transport by air, on water and on rail networks with the exclusion of machinery mounted on those means of transport. Means of transport by road that are not yet covered by a specific Union legal act should be regulated by this Regulation with the exception of the risks that may arise from the circulation. This means that vehicles, including e-bikes, e-scooters and other personal mobility devices that are not subject to EU type approval under Regulation (EU) No 167/2013⁸ or Regulation (EU) No 168/2013⁹ or approval under Regulation (EU) 2018/858 are covered by this Regulation.*

⁷ Directive (EU) 2017/853 of the European Parliament and of the Council of 17 May 2017 amending Council Directive 91/477/EEC on control of the acquisition and possession of weapons (OJ L 137, 24.5.2017, p. 22).

⁸ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

⁹ Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

- (16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and **electrical** motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council¹⁰ and should therefore be excluded from the scope of this Regulation. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council¹¹ as radio equipment. Those products should also be excluded from the scope of this Regulation.
- (17) The evolution of the machinery sector has resulted in the growing use of digital means and software plays a more and more important role in the machinery design. Consequently, the definition of machinery should be adapted. In this respect, machinery missing only the upload of a software intended for the specific application ***foreseen by the manufacturer and which is the subject of the conformity assessment procedure*** of the machinery should fall under the definition of machinery and not under the ***definitions of related products or*** partly completed machinery. Furthermore, the definition of safety components should cover not only physical devices but also digital devices. In order to take into account the increasing use of software as a safety component, software that performs a safety function and is placed independently on the market should be considered a safety component.
- (17a) Considering their critical protective function, certain components included in the indicative list of safety components in Annex II should also be subject to specific conformity assessment procedure and included in Annex I.***

¹⁰ Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast) (OJ L 96, 29.3.2014, p. 357).

¹¹ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

- (18) Partly completed machinery is a **product within the scope of this Regulation** which must undergo further construction in order to be able to perform its specific application, i.e. the well-defined operations for which the ■ product is designed. It is not necessary that all requirements of this Regulation apply to partly completed machinery but in order to ensure the safety of the ■ product as a whole, it is nevertheless important that the free movement of such partly completed machinery be guaranteed by means of a specific procedure.
- (19) Where **products within the scope of this Regulation present** risks that are addressed by the essential health and safety requirements set out in this Regulation but are also wholly or partly covered by other more specific Union legislation, this Regulation should not apply to the extent that those risks are covered by that other Union legislation. In other cases, ■ products **within the scope of this Regulation may present** risks that are not covered by the essential health and safety requirements set out in this Regulation. For example, ■ products incorporating a Wi-Fi function **may present** risks not addressed by the essential health and safety requirements set out in this Regulation, as this Regulation does not deal with risks specific to such systems. ■
- (20) For trade fairs, exhibitions and similar events, it should be possible to exhibit **products within the scope of this Regulation** which do not meet the requirements of this Regulation, since this would not **present** any safety risk. However, for the sake of transparency, interested parties should be properly informed that the **products within the scope of this Regulation** are not compliant and cannot be purchased.
- (21) The evolution of the state of the art in the machinery sector has an impact on the classification of **machinery or related** products **listed in Annex I**. **With a view to** properly reflecting **any machinery or related** products **presenting a higher risk factor**, criteria should be established for the assessment **of products which** should be included in the list of **machinery or related** products **subject to a stricter conformity assessment procedure**.

- (22) Other risks related to new digital technologies are those provoked by malicious third parties that have an impact on the safety of *products within the scope of this Regulation*. In this respect, manufacturers should be required to adopt proportionate measures which are limited to the protection of the safety of the *product within the scope of this Regulation*. This does not preclude the application to *products within the scope of this Regulation* of other Union legislation specifically addressing cybersecurity aspects.
- (23) In order to ensure that machinery *or related* products, when placed on the market or put into service, do not entail health and safety risks for persons or domestic animals and do not cause harm to property and, where applicable, the environment, essential health and safety requirements should be set out which have to be met in order for the machinery *or related* products to be allowed on the market. Machinery *or related* products should comply with the essential health and safety requirements when placed on the market or put into service. Where such ■ products are subsequently modified, by physical or digital means, in a way that is not foreseen *nor planned* by the manufacturer and *which affects the safety of such products by creating a new hazard or increasing an existing risk*, the modification should be considered as substantial *when new significant protective measures are required*. ***However, repair and maintenance operations which do not affect the machinery or related product's compliance with the relevant essential health and safety requirements should not be considered to be substantial modifications.*** In order to ensure the compliance of such a ■ product with the relevant essential health and safety requirements, the person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified ■ product on the market or putting it into service. ■ In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the machinery *or related* product that are not impacted by the modification. ■

- (24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to reduce the regulatory burden on SMEs, **it is important that** notified bodies **consider adapting** the fees for conformity assessments and **reducing** them proportionately to the specific interests and needs of SMEs.
- (25) Economic operators should be responsible for the compliance of **products within the scope of this Regulation** with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as **protection of** the health and safety of persons, **in particular consumers and professional users**, where appropriate, domestic animals, property and, where applicable, the environment , as well as the fair competition on the Union market.
- (26) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only **products within the scope of this Regulation**, which are in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations, which correspond to the role of each economic operator in the supply and distribution chain.
- (27) In order to facilitate communication between economic operators, market surveillance authorities and users, Member States should encourage economic operators to include a website, **email address or other digital contact** in addition to the postal address.
- (28) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

- (29) The manufacturer **■** should also ensure that a risk assessment is carried out for the ***product within the scope of this Regulation***, which the manufacturer wishes to place on the market or put into service. ***In this context***, the manufacturer should determine which of the essential health and safety requirements that are applicable to the ***product within the scope of this Regulation*** and in respect of which measures must be taken to address the risks that the **■** product may present. **■** The risk assessment should ***also address future updates or developments of a software installed in the machinery or related product, which are foreseen when the machinery or related product is placed on the market or put into service. The risks identified during the risk assessment should include those risks that may appear during the product's lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy.***
- (30) The safety of the ***entire machinery or related product*** relies on the dependencies and interactions between its components, ***including*** partly completed machinery, ***and, if relevant, with other machinery or related product*** that participate in a coordinated assembly of a machinery system, ***which can also result in an assembly of machinery.*** Therefore, manufacturers should be required to assess all those interactions in the risk assessment. **■**
- (31) It is essential that, before drawing up the EU declaration of conformity **■** or the ***EU declaration of incorporation, the manufacturer*** prepares a technical ***documentation***, which ***the manufacturer*** should be required to make available to national authorities ***on request or to notified bodies in the frame of the relevant conformity assessment procedure.*** Detailed plans of subassemblies used for the manufacture of the ***product within the scope of this Regulation*** should only be required as part of the technical ***documentation*** where knowledge of such plans is essential for **■** assessing conformity with the essential health and safety requirements set out in this Regulation.

- (31a) *A person who manufactures machinery or related products for his or her own use is considered as a manufacturer and must fulfil all the related obligations. In that case, the machinery or related product is not placed on the market, since it is not made available by the manufacturer to another person but used by the manufacturer himself or herself. However, such machinery must comply with this Regulation before it is put into service.*
- (32) It is necessary to ensure that **products within the scope of this Regulation** from third countries entering the Union market comply with the requirements of this Regulation and do not **present** a risk to the health and safety of persons, **in particular consumers and professional users**, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such **products**. Provision should therefore be made for importers to ensure that **products within the scope of this Regulation** that they place on the market comply with the requirements of this Regulation and do not **present** a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking, **in case of machinery and related products, is affixed** and technical documentation drawn up by manufacturers is available for inspection by the competent national authorities.
- (33) As the distributor makes **products within the scope of this Regulation** available on the market after they have been placed on the market by the manufacturer or the importer, the distributor should act with due care to ensure that his or her handling of the **product within the scope of this Regulation** does not adversely affect its compliance with the requirements set out in this Regulation.

- (34) When placing *products within the scope of this Regulation* on the market, the importer should indicate on *these products* his or her name, registered trade name or registered trade mark, *website, email address or other digital contact* and the postal address at which he or she can be contacted. Exceptions should be provided for in cases where the size or nature of the  product does not allow it. This includes cases where the importer would have to open the packaging to put his or her name and address on the  product.
- (35) In view of ensuring the health and safety of the users of *products within the scope of this Regulation*, economic operators should ensure that all relevant documentation, such as the *instructions for use*, whilst containing precise and comprehensible information, is easily understandable *and available in a language which can be easily understood by users, as determined by the Member State concerned*, takes into account technological developments and changes to *user* behaviour, and is as up to date as possible. When *products within the scope of this Regulation* are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.
- (35a) *Instructions and other relevant documentation may be provided in a digital printable format. However, the manufacturer should ensure that distributors can provide, upon request of the purchaser at the time of the purchase, the instructions for use in a paper format free of charge. The manufacturer should also consider providing the contact details where the purchaser can request the instructions to be dispatched by mail.*
- (36) Any economic operator who either places a *product within the scope of this Regulation* on the market under his or her own name or trademark or modifies a *product within the scope of this Regulation* in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

- (37) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the *product within the scope of this Regulation* concerned.
- (38) Ensuring traceability of *products within the scope of this Regulation* throughout the whole supply chain enables a simpler and more efficient market surveillance. The economic operators should therefore be required to keep the information on their transactions of *products within the scope of this Regulation* for a certain period of time. However, that obligation should be proportionate to the role of each economic operator in the supply chain and the economic operators should not be required to update information that they have not produced.
- (39) This Regulation should be limited to setting out the essential health and safety requirements, supplemented by a number of more specific requirements for certain categories of *products within the scope of this Regulation*. In order to facilitate the assessment of conformity with those health and safety requirements it is necessary to provide for a presumption of conformity for *products within the scope of this Regulation* which *are* in conformity with harmonised standards that are developed and which references are published in the *Official Journal of the European Union* ■ in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council¹² for the purpose of expressing detailed technical specifications of those requirements.

¹² Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- (40) *The current EU standardisation framework which is based on the New Approach principles and on Regulation (EU) No 1025/2012 represents the framework by default to elaborate standards that provide presumption of conformity with the relevant essential health and safety requirements of this Regulation. European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission's request to one or more European standardisation organisations to draft harmonised standards, within a set deadline and be based on consensus. However, in the absence of relevant references to harmonised standards, the Commission should be able to establish, via implementing acts, common specifications for the essential health and safety requirements of this Regulation, provided that in doing so it duly respects the standardisation organisations' role and functions, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with the health and safety requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications.*
- (40a) *With a view to establishing, in the most efficient way, common specifications that cover the essential health and safety requirements of this Regulation, the Commission should involve relevant stakeholders in the process.*
- (40b) *Reasonable period should mean, in relation to the publication of reference to harmonised standards in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, a period of time in which the publication of reference to the standard, its corrigendum or amendment in the Official Journal of the European Union is expected and which should not exceed the period of 1 year after the deadline set in accordance with Article 10(1) of the Regulation (EU) No 1025/2012.*

- (41) Compliance with harmonised standards and with *common* specifications established by the Commission should be voluntary. Alternative technical solutions should therefore be acceptable where compliance of *products within the scope of this Regulation* with the relevant essential health and safety requirements is demonstrated in the technical file.
- (42) The essential health and safety requirements should be satisfied in order to ensure that the *product within the scope of this Regulation* is safe. Those requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.
- (43) In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of *products within the scope of this Regulation*, this Regulation should include essential health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to and in accordance with Article 54(3) of Regulation (EU) 2019/881 of the European Parliament and of the Council¹³.
- (44) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not satisfy or entirely satisfy the requirements of this Regulation.

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¹³ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).

- (46) Manufacturers should draw up an EU declaration of conformity to provide information on the conformity of machinery *or related* products with this Regulation. Manufacturers may also be required to draw up an EU declaration of conformity by other Union legislation. To ensure effective access to information for market surveillance purposes, a single EU declaration of conformity should be drawn up in respect of all Union acts. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.
- (46a) *The harmonised standards relevant to this Regulation should take into account the requirements of Directive (EU) 2019/882 (European Accessibility Act) and the United Nations Convention on the Rights of Persons with Disabilities¹⁴.*
- (46b) *The list of products in Annex IV of Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of those products or their critical protective function. Nevertheless, the machinery field embraces new ways of designing and constructing machinery or related products that may present higher risk factors, regardless of such intended use or any reasonably foreseeable misuse. For example, systems with self evolving behavior ensuring safety functions, should be included in Annex I due to their characteristics such as data dependency, opacity, autonomy and connectivity, which might considerably increase the probability and severity of harm and seriously affect the safety of the machinery or related product. Therefore, the conformity assessment of a safety components or a system with self evolving behavior ensuring safety functions should be carried out by a third party, whether or not the safety component has been placed independently on the market or is part of a system embedded in machinery that is placed on the market. However, machinery that embeds a system where the safety component has already been subject to third party conformity assessment when it was placed independently on the market should not have to be re-certified by a third party solely on the basis of it embedding that system.*

¹⁴ *OJ L 23, 27.1.2010, p. 35.*

- (46c) *Provisions related to the third-party conformity assessment of software ensuring safety functions set out in this Regulation should only apply to systems with a fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions. On the contrary, those provisions should not apply to software incapable of learning or evolving, and programmed only to execute certain automated functions of machinery or related products.*
- (47) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on machinery *or related* products should be laid down in this Regulation.
- (48) The CE marking should be the only marking, which guarantees that machinery *or related* products comply with the requirements of this Regulation. Member States should therefore take appropriate action as regards other markings which are likely to mislead third parties as to the meaning or the form of the CE marking.
- (49) In order to enable economic operators to demonstrate and the competent authorities to ensure that machinery *or related products* made available on the market *are* in conformity with the essential health and safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (50) Manufacturers should be responsible for *ensuring that a conformity assessment is carried out in respect* of their machinery *or related* products *in accordance* with this Regulation. Nevertheless, for certain *categories* of machinery *or related* products that have a higher risk factor, a stricter *conformity assessment* procedure requiring *the* participation of a notified body should be required.

- (51) It is essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (52) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (53) In order to ensure a consistent level of quality in the performance of conformity assessment of machinery *or related* products, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (54) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (55) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

- (56) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the machinery to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.
- (57) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (58) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (59) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Union legislation. It is therefore appropriate to put in place a legal framework within which market surveillance can be carried out in an appropriate manner.

- (60) Member States should take all appropriate measures to ensure that machinery *within the scope of* this Regulation may be placed on the market *or put into service* only if, when properly installed and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons, *in particular consumers and professional users*, and, where appropriate, domestic animals and property and, where applicable, the environment. *In particular, the proper installation of lifting machinery is essential to ensure the compliance with applicable essential health and safety requirements. Machinery within the scope of* this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour.
- (61) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on *products within the scope of this Regulation* and the safeguard clause relating to *products within the scope of this Regulation*.
- (62) Directive 2006/42/EC already provides for a safeguard procedure, which is necessary to allow for the possibility of contesting the conformity of *products within the scope of this Regulation*. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (63) The existing safeguard procedure should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to *products within the scope of this Regulation* posing ■ a risk to the health or safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment. It should allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such ■ products.

- (64) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (65) In order to take into account technical progress and knowledge or new scientific evidence **and to ensure a sufficient level of data availability**, 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 amending the list of **machinery and related** products and the indicative list of safety components **in Annex I and Annex II, and if necessary of supplementing the obligations of Member States to communicate information on the categories of machinery and related products which are subject to a specific conformity assessment procedure through the establishment of a common methodology. Where a new machinery or related product is added to the list in Annex I, the Commission should ensure that economic operators are provided with sufficient time to comply with their obligations under this Regulation.** It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including **the stakeholders concerned**. 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.

- (66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing ***a uniform template for the collection of data and information for the purpose of adding a category of machinery or related product to Annex I or withdrawing a category of machinery or related product from Annex I, and establishing common*** specifications for the essential health and safety requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to **█** pose a risk to health and safety of persons, ***in particular consumers and professional users*** is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁵.
- (66a) ***In order to facilitate the proper implementation of this Regulation, when adopting the implementing acts setting out and updating a template concerning the collection of the data and the information by the Member States on accidents or damage to health caused by machinery or related products, the Commission should adopt a guidance regarding the collection and transmission of comparable, high-quality data and information.***
- (67) The Commission should adopt immediately applicable implementing acts determining whether a national measure taken in respect of compliant ***products within the scope of this Regulation*** that poses a risk is justified or not where, in duly justified cases relating to the protection of the health or safety of persons, imperative grounds of urgency so require.
- (68) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

¹⁵ 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).

- (69) When matters relating to this Regulation, other than its implementation or infringements, are being examined in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (70) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant ***products within the scope of this Regulation*** are justified or not.
- (71) The traceability of machinery data required for the technical file and for market surveillance purposes, must comply with confidentiality rules to protect manufacturers.
- (72) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (73) Since the objective of this Regulation, namely to ensure that ***products within the scope of this Regulation*** placed on the market fulfils the requirements providing for a high level of protection of health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of the need for harmonisation, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity 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.

- (74) Council Directive 73/361/EEC¹⁶ on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks should be repealed as Directive 2006/42/EC took over its scope by including *machinery or* lifting accessories and chains and ropes.
- (75) Directive 2006/42/EC has been amended several times. Since further substantial amendments are needed, and in order to ensure a uniform implementation of the rules on *products within the scope of this Regulation* throughout the Union, Directive 2006/42/EC should be repealed.
- (76) It is necessary to provide for sufficient time for economic operators to comply with their obligations under this Regulation, and for Member States to set up the administrative infrastructure necessary for its application. The application of this Regulation should therefore be deferred,

HAVE ADOPTED THIS REGULATION:

¹⁶ Council Directive 73/361/EEC of 19 November 1973 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks (OJ L 335, 5.12.1973, p. 51).

CHAPTER I

GENERAL PROVISIONS

Article 1 Subject matter

This Regulation lays down **health and safety** requirements for the design and construction of machinery, **related** products **and partly completed machinery** to allow **their** making available on the market or putting into service **while ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, domestic animals and property and, where applicable, the environment. It also** establishes rules on the free movement of **these** products in the Union.

Article 2 Scope

(1) This Regulation applies to **machinery and** the following **related** products:

■

- (b) interchangeable equipment;
- (c) safety components;
- (d) lifting accessories;
- (e) chains, ropes ■ and webbing;
- (f) removable mechanical transmission devices.

■

This Regulation also applies to partly completed machinery.

- (2) This Regulation does not apply to:
- (a) safety components that are intended to be used as spare parts to replace identical components and are supplied by the manufacturer of the original machinery, ***related product or partly completed machinery***;
 - (b) specific equipment for use in fairgrounds or amusement parks;
 - (c) machinery ***and related products*** specially designed ***for use within or used in a nuclear installation and whose conformity with this Regulation may undermine the nuclear safety***;
 - (d) weapons, including firearms;
 - (e) ***means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport***;
 - (ea) ***aeronautical products, parts and equipment that fall within the scope of application of Regulation (EU) 2018/1139 of the European Parliament and of the Council¹⁷ and the definition of machinery under this Regulation, as far as in as much as Regulation (EU) 2018/1139 covers the relevant health and safety requirements set out in this Regulation***;
 - (eb) ***motor vehicles and their trailers, as well as systems, components and separate technical units, parts and equipment designed and constructed for such vehicles, which fall within the scope of application of Regulation (EU) 2018/858, except for machinery mounted on those vehicles***;

¹⁷ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

- (f) two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) No 168/2013, ***except for machinery mounted on those vehicles;***
- (g) agricultural and forestry ***tractors***, as well as systems, components, separate technical units, parts and equipment designed and constructed for such ***tractors***, that fall within the scope of application of Regulation (EU) No 167/2013 ***with the exception of machinery mounted on those tractors;***
- (ga) motor vehicles exclusively intended for competition;***
- (h) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;
- (i) machinery ***or related products*** specially designed and constructed for military or police purposes;
- (j) machinery ***or related products*** specially designed and constructed for research purposes for temporary use in laboratories;
- (k) mine winding gear;
- (l) machinery ***or related products*** intended to move performers during artistic performances;

- (m) the following electrical and electronic products, insofar as they fall within the scope of application of Directive 2014/35/EU or Directive 2014/53/EU:
 - (i) household appliances intended for domestic use which are not electrically operated furniture;
 - (ii) audio and video equipment;
 - (iii) information technology equipment;
 - (iv) **ordinary** office machinery, **except additive printing machinery for producing three-dimensional products**;
 - (v) low-voltage switchgear and control gear;
 - (vi) electric motors;
- (n) the following high-voltage electrical products:
 - (i) switch gear and control gear;
 - (ii) transformers.

Article 3 Definitions

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

- (1) 'machinery' means:
 - (a) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;
 - (b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion;
 - (c) an assembly referred to points (a) and (b), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure;
 - (d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point **(10)** which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;
 - (e) an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;
 - (f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for *the* specific application ***foreseen by the manufacturer***.

- (2) ‘interchangeable equipment’ means a device which, after the putting into service of a machinery *or an agricultural or forestry tractor*, is assembled with that machinery *or agricultural or forestry tractor* by the operator **■** in order to change its function or attribute to it a new function, in so far as that equipment is not a tool;
- (3) ‘safety component’ means a physical or digital component, including software, of *products within the scope of this Regulation*, which *is designed or intended* to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the *products within the scope of this Regulation* to function or may be substituted by normal components in order for *those products* to function;
- (3a) *‘safety function’ means a function that serves to fulfil a protective measure, designed to eliminate, or, if that is not possible, to reduce, a risk and where its failure can result in an increase of the risk;*
- (4) ‘lifting accessory’ means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market, including slings and their components;
- (5) ‘chains’ means chains designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;
- (6) ‘ropes’ means ropes designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;
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- (8) ‘webbing’ means webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

- (9) ‘removable mechanical transmission device’ means a removable component for transmitting power between self-propelled machinery or a tractor and another *machinery* by joining them at the first fixed bearing. ***When it is placed on the market with the guard it shall be regarded as one item;***
- (10) ‘partly completed machinery’ means an assembly which is ***not yet machinery as*** it cannot in itself function so as to perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery ■ ;
- (11) ‘making available on the market’ means any supply of a ***product within the scope of this Regulation a*** for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (12) ‘placing on the market’ means the first making available of a ***product within the scope of this Regulation*** on the Union market;
- (13) ‘putting into service’ means the first use, for its intended purpose, in the Union, of ■
machinery or related products;
- (13a) ***‘essential health and safety requirements’ means mandatory provisions relating to the design and construction of the products within the scope of this Regulation to ensure a high level of protection of the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, as set out in Annex III;***
- (14) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;

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- (16) ‘substantial modification’ means a modification of a machinery **or related** product, by physical or digital means after that machinery **or related** product has been placed on the market or put into service, which is not foreseen **or planned** by the manufacturer, **and which affects the safety of that machinery or related product, by creating a new hazard or by increasing an existing risk, which requires:**
- (i) **the addition of guards or protective devices to that machinery or related product whose processing modifies the existing safety control system, or**
 - (ii) **the adoption of additional protective measures to ensure the stability or mechanical strength of that machinery or related product;**
- (17) ‘manufacturer’ means any natural or legal person who (i) manufactures **products within the scope of this Regulation** or who has **those** products designed or manufactured, and markets those **■** products under his or her name or trademark or (ii) **manufactures products within the scope of this Regulation, and puts those products into service** for his or her own use;
- (18) ‘instructions for use’ means the information provided by the manufacturer when the machinery **or related** product is placed on the market or put into service to inform the user of the machinery **or related** product of the intended **and** proper use of that machinery **or related** product, as well as information on any precautions to be taken when using or installing the machinery **or related** product, including information on the safety aspects **and on how to keep that machinery or related product safe and ensure that it remains "fit for purpose" during its entire lifetime;**
- (19) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;
- (20) ‘importer’ means any natural or legal person established within the Union who places **a product within the scope of this Regulation** from a third country on the Union market;

- (21) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes *a product within the scope of this Regulation* available on the market;
- (22) ‘economic *operator*’ means the manufacturer, the authorised representative, the importer and the distributor;
- (23) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by *products within the scope of this Regulation*;
- (24) ‘harmonised standard’ means a harmonised standard as defined in Article 2(1), point (c) of Regulation (EU) No 1025/2012;
- (25) ‘CE marking’ means a marking by which the manufacturer indicates that a machinery *or related* product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (26) ‘accreditation’ means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;
- (27) ‘national accreditation body’ means a national accreditation body as defined in Article 2, *point* (11) of Regulation (EC) No 765/2008;
- (28) ‘conformity assessment’ means the process demonstrating whether the *applicable* essential health and safety requirements of this Regulation relating to machinery *or related* products have been fulfilled;
- (29) ‘conformity assessment body’ means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;
- (30) ‘notified body’ means a conformity assessment body notified in accordance with Article 28 of this Regulation;

- (31) ‘market surveillance authority’ means a market surveillance authority as defined in Article 3, point (4) of Regulation (EU) 2019/1020;
- (32) ‘recall’ means any measure aimed at achieving the return of a *product within the scope of this Regulation* that has already been made available to the *user*;
- (33) ‘withdrawal’ means any measure aimed at preventing a *product within the scope of this Regulation* in the supply chain from being made available on the market.
- (33a) *‘lifetime’ means the period from the moment that a machinery or related product is placed on the market or put into service until the moment that it is discarded, including the effective time when the machinery or related product is capable of being used and the phases of transport, assembly, dismantling, disabling, scrapping or other physical or digital modifications foreseen by the manufacturer;*
- (33b) *‘source code’ means the currently installed version of the software of a product within the scope of this Regulation, written in a programming language so that it is unambiguous, understandable to humans;*
- (33c) *‘professional user’ means a natural person who uses or operates a machinery or related product in the course of his or her professional activity or work.*

Article 4
Free movement

1. Member States shall not impede, for reasons relating to the aspects covered by this Regulation, the making available on the market ***of products within the scope of this Regulation*** or the putting into service of machinery ***or related*** products which comply with this Regulation.
2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a ***product within the scope of this Regulation*** which does not comply with this Regulation, provided that a visible sign clearly indicates that it does not comply with this Regulation and will not be available on the market until it has been brought into conformity.

During demonstrations, adequate measures shall be taken to ensure the protection of persons.

Article 4a

Protection of persons during installation or use of machinery or related products

Member States may lay down requirements to ensure that persons, including workers, are protected when installing or using machinery or related products, provided that such rules do not allow for modification of a machinery or related product in a way that is not compatible with this Regulation.

Article 5

Categories of machinery and related products listed in Annex I subject to relevant conformity assessment procedures set out in Article 21

1. ***Machinery and related products that fall within the categories listed in Annex I, part A, shall be subject to the specific conformity assessment procedures, as referred to in Article 21(2), and those in part B may be subject to the specific conformity assessment procedures, as referred to in Article 21(2a).***
2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, ***after consulting the stakeholders concerned***, in view of technical progress and knowledge or new scientific evidence by ***adding to*** the list of ***categories of machinery and related products in Annex I*** a new ***category of machinery or related product*** or withdrawing an existing ***category of machinery or related product*** from that list, pursuant to the criteria ***and the procedure*** laid down in paragraphs 3, 4 and 6.
- 2a. ***Before adopting a delegated act, the Commission shall gather the views of experts in the relevant expert groups in accordance with article 45(3).***

3. ***The Commission shall assess the seriousness of the inherent potential risk for the purpose of adding a category of machinery or related product to Annex I or withdrawing a category of machinery or related product from Annex I. That assessment shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.***

In determining the probability and severity of harm, the following ***criteria*** shall be taken into account, ***where relevant***:

(-a) the nature of the hazard inherent to the function of the machinery or related product category, taking into account the intended use and reasonably foreseeable misuse;

- (a) the severity of harm by which a person would be affected, including the degree of reversibility of such harm;***
- (b) the number of persons potentially affected by the harm;;***
- (c) the frequency and the duration of the exposure to the hazard that a person would be exposed to in course of the intended use or reasonably foreseeable misuse of the category of machinery or related product;***
- (d) the possibilities of avoiding or limiting harm;***

(da) in case of safety components, the likelihood of serious consequences for the safety of the persons exposed in the event of failure.

4. ***When conducting the assessment referred in the previous paragraph, the Commission shall consider the following elements:***

(a) ***indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or following any reasonably foreseeable misuse;***

■
(aa) ***information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;***

■
(ab) ***known accidents and serious close calls, including characteristics of these accidents or close call;***

(d) ***data on accidents or damage to the health caused by the machinery or related product at least for the preceding four years. In particular information obtained, among others, from the Information and Communication System for Market Surveillance (ICSMS) ■ , safeguard clauses, Rapid Alert System (RAPEX), the European Injury Database (EU-IDB), the Eurostat European Statistics on Accidents at Work (ESAW) and the Machinery Administrative Cooperation Group (AdCo).***

In addition to points (a) to (d), the Commission shall take into account any other available information relevant for the assessment referred to in paragraph 3.

- 4a.** *The data and information referred to in the previous paragraph a) to d) shall be provided by Member States in accordance with paragraph 5.*
- 4b.** *When the seriousness of its inherent potential risk is established according to the assessment referred to in paragraph 3 taking into account the available information, including the data referred to in paragraph 4, a category of machinery or related product shall be included in Annex I, Part A provided that at least one of the following conditions is fulfilled:*
- (i)** *lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;*
 - (ii)** *existence of residual risks including those which could be reduced by particular training or personal protective equipment according to the manufacturer and for which data and information set out in paragraph 4 demonstrate the recurrence of similar serious or fatal accidents or damage to health in relation with these residual risks;*
 - (iii)** *data and information which according to the Commission demonstrate recurring wrongful application of the relevant harmonised standards or common specifications and for which conducted market surveillance activities have not lead to major improvements of the market situation, in a reasonable period of time;*
 - (iv)** *the existence of a degree of uncertainty of the existing risk assessment methods related to new categories of machinery or technologies.*
- Any other category of machinery or related product for which the seriousness of its inherent potential risk is established according to the assessment referred to in paragraph 3 shall be included in Annex I, Part B.*

- 4c. *A Member State which has concerns about a category of machinery or related product being listed or not in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.*

The Commission shall conduct the assessment referred to in paragraph 3 immediately after having been informed by a Member State.

After that assessment the Commission may initiate the procedure laid down in paragraph 2.

5. *By 24 months after the date of the entry into force of this Regulation, and every 5 years thereafter, Member States shall provide the data and information referred to in paragraph 4, including information that no event referred to in paragraph 4 occurred, for any category of machinery or related products which is included in Annex I or for which a Member State has concerns about not being included in Annex I.*

5a. The Commission shall adopt implementing acts setting out and, where necessary in view of technological and market development, updating a template concerning the collection of the data and the information by the Member States referred to in paragraph 4(a) to (d).

When adopting the implementing acts, the Commission shall adopt guidance to Member States on the collection and transmission of comparable, high-quality data and information.

Those implementing acts shall be adopted in accordance with the [examination] procedure referred to in Article 46(3).

The first such implementing act shall be adopted not later than 12 months after the entry into force of this Regulation.

5b. The Commission shall, if necessary after the Commission report referred to in Article 51(2a), adopt delegated acts to supplement paragraph 4 of this Article by specifying Member States' obligation to provide data and information required pursuant to this Article through the establishment of a common methodology on the data and information to be collected, including the relevant definitions, methods for their collection and compilation, and the procedures for its transmission, in order to ensure that sufficient and comparable data is available for the Commission to carry out the assessment referred to in paragraph 3.

Those delegated acts shall be adopted in accordance with Article 45.

Article 6
Safety components

1. An indicative list of safety components is set out in Annex II.
 2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex II in view of technical progress and knowledge or new scientific evidence by including a new safety component in the indicative list of safety components or withdrawing an existing safety component from that list.
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4. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately inform the Commission of its concerns and provide reasons in support thereof.

Article 7

Essential health and safety requirements for products within the scope of this Regulation

Machinery ***or related*** products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended ***use*** or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III.

Partly completed machinery shall only be made available on the market if they meet the relevant essential health and safety requirements set out in Annex III.

Article 8

Specific Union harmonisation legislation

Where, for a certain ***product within the scope of this Regulation***, the risks addressed by the essential health and safety requirements set out in Annex III are wholly or partly covered by other more specific Union harmonisation legislation, this Regulation shall not apply to that ***product within the scope of this Regulation*** to the extent that that specific Union legislation covers such risks.

CHAPTER II OBLIGATIONS OF ECONOMIC OPERATORS

Article 10

Obligations of manufacturers *of machinery and related products*

1. When placing a machinery *or a related* product on the market *or putting it into service*, manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III.
2. Before placing a machinery *or related* product on the market *or putting it into service*, manufacturers shall draw up the technical documentation *set out in part A of Annex IV* and carry out the relevant conformity assessment *procedure* referred to in Article 21 or *have it* carried out.

Where compliance of *a* machinery *or related* product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity in accordance with Article 18 and affix the CE marking in accordance with Article 20 **■** .

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity **■** at the disposal of the market surveillance authorities for ten years after the machinery *or the related* product has been placed on the market *or put into service*. Where relevant, the source code or *programming* logic included in the technical documentation shall be made available upon a reasoned request from the competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.

4. Manufacturers shall ensure that procedures are in place for machinery *or related* products that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the machinery *or related* product and changes in the harmonised standards or *other* technical *specifications or in the common* specifications referred to in Article 17 by reference to which the conformity of the machinery *or related product is declared* shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by machinery *or related* products, manufacturers shall, *in order* to protect the health and safety of *users*, carry out sample testing of machinery *or related* products made available on the market *and* investigate *their results*. If necessary, *manufacturers shall* keep a register of complaints, of non-conforming machinery *or related* products and machinery *or related products* recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that the machinery *or related product* which they place on the market *or put into service* bears *at least a designation of the machinery, series or type, the year of construction, that is the year in which the manufacturing process is completed, and, if any,* batch or serial number or other element allowing its identification, or, where the size or nature of the machinery *or related* product does not allow it, that the required information is provided on the packaging or in a document accompanying the machinery *or related* product.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and the *website, e-mail address or other digital contact* at which they can be contacted on the machinery *or related* product or, where that is not possible, on its packaging or in a document accompanying the machinery *or related products*. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by *users* and market surveillance authorities.
7. Manufacturers shall ensure that the machinery *or related* products are accompanied by the instructions *for use* and information set out in **■** Annex III. *The instructions may be provided in a digital format. ■* Such instructions and information shall *clearly describe the product model to which they correspond*.

When the instructions for use are provided in digital format, the manufacturer shall:

- (a) mark on the machinery or related product, and on the packaging or in an accompanying document how to access the digital instructions;*
- (b) present them in a format that makes it possible for the user to print and download the instructions for use and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machinery or related product. This requirement also applies where the instructions for use are embedded in the software of the machinery or related product;*

- (c) *make them accessible online during the expected lifetime of the machinery or related product and not less than 10 years after the placing on the market of the machinery or related product.*

However, upon request of the user at the time of the purchase, the manufacturer shall provide the instructions for use in paper format free of charge within one month.

In the case of a machinery or related product intended for non-professional users or which can, under reasonably foreseeable conditions, be used by non-professional users even if not intended for them, the manufacturer shall provide in paper format the safety information that are essential for putting the machinery or related product into service and for using it in a safe way.

The instructions for use and information shall be in a language which can be easily understood by users, as determined by the Member State concerned and shall be clear, understandable, intelligible and legible.

8. Manufacturers shall *ensure that the machinery or related products is accompanied by the EU declaration of conformity set out in Part A of Annex V or shall provide the internet address at which it can be accessed in the instructions for use and information set out in section 1.7 of Annex III.*

Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the machinery or related product and not less than 10 years after placing on the market or putting into service of the machinery or related product.

9. Manufacturers who consider or have reason to believe that a machinery *or related* product, which they have placed on the market or put into service is not in conformity with *this Regulation* shall immediately take the corrective *actions* necessary to bring that machinery *or related* product into conformity, to withdraw it or to recall it, as appropriate.
Furthermore, where the machinery *or related* product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery *or related* product available on the market *or put into service* to that effect, giving details, in particular, of the non-conformity and of any corrective *actions* taken.
10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery *or related products with this Regulation*, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any *actions* taken to eliminate the risks *presented* by the machinery *or related products*, which they have placed on the market or put into service.

Article 10a
Obligations of manufacturers of partly completed machinery

- 1. When placing a partly completed machinery on the market, manufacturers shall ensure that it has been designed and constructed in accordance with the relevant essential health and safety requirements set out in Annex III.**
- 2. Before placing a partly completed machinery on the market, manufacturers shall draw up the technical documentation set out in part B of Annex IV.**
Where compliance of a partly completed machinery with the relevant essential health and safety requirements laid down in Annex III has been demonstrated in the technical documentation set out in Part B of Annex IV, manufacturers shall draw up the EU declaration of incorporation in accordance with Article 18a.
- 3. Manufacturers shall keep the technical documentation and the EU declaration of incorporation at the disposal of the market surveillance authorities for ten years after the partly completed machinery has been placed on the market.**
- 4. Manufacturers shall ensure that procedures are in place for partly completed machinery that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the partly completed machinery and changes in the harmonised standards or other technical specifications or in the common specifications referred to in Article 17 by reference to which the conformity of the partly completed machinery is declared or by application of which its conformity is verified shall be adequately taken into account.**

5. *Manufacturers shall ensure that the partly completed machinery which they place on the market bears at least the designation of the partly completed machinery, the year of construction, that is the year in which the manufacturing process is completed, model and series or type and, if any, batch or serial number or other element allowing its identification, or, where the size or nature of the partly completed machinery does not allow it, that the required information is provided on the packaging or in a document accompanying the partly completed machinery.*
6. *Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery into a machinery and market surveillance authorities.*

7. *Manufacturers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X.*

The assembly instructions may be provided by the manufacturer in digital format.

When the assembly instructions are provided in digital format, the manufacturer shall:

- (a) mark on the partly completed machinery, and on the packaging or in an accompanying document how to access the digital assembly instructions;*
- (b) present them in a format that makes it possible for the person who incorporates the partly completed machinery to print and download the assembly instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the partly completed machinery. This requirement also applies where the assembly instructions are embedded in the software of the partly completed machinery;*
- (c) make them accessible online for not less than 10 years after the placing on the market of the partly completed machinery.*

However, at the time of purchase upon request of the person who incorporates the partly completed machinery, the manufacturer shall provide the assembly instructions in paper format free of charge within one month.

The assembly instructions shall be in a language which can be easily understood by the person who incorporates the partly completed machinery, as determined by the Member State concerned and shall be clear, understandable, intelligible and legible.

8. *Manufacturers shall ensure that the partly completed machinery is accompanied by the EU declaration of incorporation set out in Part B of Annex V or shall provide the internet address at which it can be accessed in the assembly instructions set out in Annex X.*

Digital EU declarations of incorporation shall be made accessible online for at least 10 years after placing on the market of the partly completed machinery.

9. *Manufacturers who consider or have reason to believe that a partly completed machinery which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards the essential health and safety requirements, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.*
10. *Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks as regards the essential health and safety requirements presented by the partly completed machinery, which they have placed on the market.*

Article 11
Authorised representatives

1. A manufacturer *of a product within the scope of this Regulation* may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 10(1) and *Article 10a(1)* and the obligation to draw up the technical documentation *set out in Annex IV* shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - (a) keep the *technical documentation and the EU declaration of conformity of machinery and related products or the EU declaration of incorporation of partly completed machinery* at the disposal of the national market surveillance authorities for **█** *not less than* ten years after the **█** product has been placed on the market;
 - (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the *product within the scope of this Regulation. It could be either in paper or digital format*;
 - (c) cooperate with the competent national authorities, at their request, on any *actions* taken to eliminate the risks *presented by a product within the scope of this Regulation* covered by the authorised representative's mandate.

Article 12
Obligations of importers *of machinery and related products*

1. Importers shall **■** place *only compliant machinery or related products on the market*.
2. Before placing a machinery *or related* product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 **■** have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation *set out in Part A of Annex IV*, that the machinery *or related* product bears the CE marking referred to in Article 19 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5) and (6).

Where an importer considers or has reason to believe that a machinery *or related* product is not in conformity with *this Regulation*, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the machinery *or related* product *presents* a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and *website*, email address *or other digital contact* at which they can be contacted on the machinery *or related* product or, where that is not possible, on its packaging or in a document accompanying the machinery *or related* product. The contact details shall be in a language easily understood by *users* and market surveillance authorities.

4. Importers shall ensure that the machinery *or related* product is accompanied by the instructions *for use* and information set out in *Article 10(7)*.
5. Importers shall ensure that *the storage or transport conditions*, while the machinery *or related* product is under their responsibility, **█** do not jeopardise *the* conformity with the essential health and safety requirements set out in Annex III.
6. When deemed appropriate with regard to the risks *presented by a machinery or related product, importers shall, in order to protect* health and safety of persons, and **█** where appropriate, domestic animals and property and, where applicable, the environment **█** carry out sample testing of machinery *or related* products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery *or related* products and machinery *or related* products recalls, and shall keep distributors informed of any such monitoring.
7. Importers who consider or have reason to believe that a machinery *or related* product, which they have placed on the market, is not in conformity with *this Regulation* shall immediately take the corrective *actions* necessary to bring that machinery *or related* product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery *or related* product *presents* a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, importers shall immediately inform the competent national authorities of the Member States in which they made the machinery *or related* product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective *actions* taken.

8. Importers shall, for ten years after the machinery *or related* product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation *set out in Part A of Annex IV* can be made available to those authorities *upon request*. Where relevant, the *importer shall arrange with the manufacturer that the* source code or *programming* logic included in the technical documentation **■** be made available upon a reasoned request from competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.
9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery *or related products with this Regulation* in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any *actions* taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment *presented by machinery or related products*, which they have placed on the market.

Article 12a
Obligations of importers of partly completed machinery

- 1. Importers shall place only compliant partly completed machinery on the market.**
- 2. Before placing a partly completed machinery on the market, importers shall ensure that the manufacturer has drawn up the technical documentation set out in Part B of Annex IV, that it is accompanied by the required documents and that the manufacturer has complied with the requirements set out in Article 10a(5) and (6).**

Where an importer considers or has reason to believe that a partly completed machinery is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a risk as regards the relevant essential health and safety requirements, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

- 3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery. The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery and market surveillance authorities.**
- 4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Article 10a(7).**

5. *Importers shall ensure that the storage or transport conditions of partly completed machinery, while it is under their responsibility, do not jeopardise the conformity with the relevant essential health and safety requirements set out in Annex III.*
6. *Importers who consider or have reason to believe that a partly completed machinery, which they have placed on the market, is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards essential health and safety requirements, importers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.*
7. *Importers shall, for ten years after the partly completed machinery has been placed on the market, keep a copy of the EU declaration of incorporation at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Part B of Annex IV can be made available to those authorities upon request in digital or paper format.*
8. *Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks presented by a partly completed machinery, which they have placed on the market.*

Article 13
Obligations of distributors *of machinery and related product*

1. When making a machinery *or related* product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
2. Before making a machinery *or related* product available on the market, distributors shall verify that:
 - (a) the machinery *or related* product bears the CE marking;
 - (b) the machinery *or related* product is accompanied by the *EU declaration of conformity* set out in *Part A* of Annex *V*;
 - (ba) the machinery or related product is accompanied by the instructions for use and information set out in Article 10(7), and that they are in a language which can be easily understood by users as determined by the Member State in which the machinery or related product is to be made available on the market;**
 - (c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.
3. Where a distributor considers or has reason to believe that a machinery *or related* product is not in conformity with *this Regulation*, the distributor shall not make the machinery *or related* product available on the market until it has been brought into conformity. Furthermore, where the machinery *or related* product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the distributor shall inform the manufacturer *or the importer* to that effect *as well as the market surveillance authorities*.

4. Distributors shall ensure that ***the storage or transport conditions***, while a machinery ***or related*** product is under their responsibility, **■** do not jeopardise ***the*** conformity with the essential health and safety requirements set out in Annex III.
5. Distributors who consider or have reason to believe that a machinery ***or related*** product, which they have made available on the market, is not in conformity with ***this Regulation*** shall make sure that the corrective ***actions*** necessary to bring that machinery ***or related*** product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery ***or related*** product ***presents*** a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery ***or related*** product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective ***actions*** taken.
6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or ***digital format***, necessary to demonstrate the conformity of the machinery ***or related product with this Regulation*** in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any ***actions*** taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, ***presented*** by a machinery ***or related*** product, which they have made available on the market.

Article 13a
Obligations of distributors of partly completed machinery

- 1. When making a partly completed machinery available on the market, distributors shall act with due care in relation to the requirements of this Regulation.**
- 2. Before making a partly completed machinery available on the market, distributors shall verify that:**
 - (a) the partly completed machinery is accompanied by the by the EU declaration of incorporation set out in part B of Annex V;**
 - (b) the partly completed machinery is accompanied by the assembly instructions set out in Article 10a(7), and that they are in a language which can be easily understood by the person who incorporates the partly completed machinery as determined by the Member State in which the partly completed machinery is to be made available on the market;**
 - (c) the manufacturer and the importer have complied with the requirements set out in Article 10a(5) and (6) and Article 12a(3) respectively.**
- 3. Where a distributor considers or has reason to believe that a partly completed machinery is not in conformity with this Regulation, the distributor shall not make the partly completed machinery available on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a risk as regards relevant essential health and safety requirements, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.**
- 4. Distributors shall ensure that the storage or transport conditions, while a partly completed machinery is under their responsibility, do not jeopardise the conformity with the relevant essential health and safety requirements set out in Annex III.**

5. *Distributors who consider or have reason to believe that a partly completed machinery which they have made available on the market, is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the partly completed machinery presents a risk as regards applicable essential health and safety requirements distributors shall immediately inform the competent national authorities of the Member States in which they have made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.*
6. *Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks as regards the essential health and safety requirements presented by a partly completed machinery, which they have made available on the market.*

Article 14

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 *and 10a* where that importer or distributor places a ***product within the scope of this Regulation*** on the market under his or her name or trademark or ***modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.***

Article 15

Other cases in which obligations of manufacturers apply

A natural or legal person, **█** that carries out a substantial modification of ***a machinery or related product*** shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for ***that machinery or related product*** **█** or, if the substantial modification has ***only*** an impact on the safety of ***a part of an assembly of machinery***, for the ***affected machinery of this assembly as demonstrated in the risk assessment.*** **█**

The person who carries out the substantial modification shall in particular and without prejudice to other obligations set out in Article 10, ensure and declare on its sole responsibility that the machinery or related product concerned is in conformity with the applicable requirements of this Regulation and shall apply the relevant conformity assessment procedure as provided in Article 21(2), (2a) and (3) of this Regulation.

A non-professional user who carries out a substantial modification on his or her own machinery or related product for his or her own use shall not be considered a manufacturer for the purposes of this Regulation and shall not be subject to the obligations of the manufacturer set out in Article 10.

Article 16
Identification of economic operators

1. Economic operators shall, on request, identify the following to the market surveillance authorities:
 - (a) any economic operator who has supplied them with a ***product within the scope of this Regulation***;
 - (b) any economic operator to whom they have supplied a ***product within the scope of this Regulation***.
2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the ***product within the scope of this Regulation*** and for ten years after they have supplied the ***product within the scope of this Regulation***.

CHAPTER III CONFORMITY OF PRODUCTS WITHIN THE SCOPE OF THIS REGULATION

Article 17

Presumption of conformity of products within the scope of this Regulation

1. A ***product within the scope of this Regulation*** which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those standards or parts thereof.
2. The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III.
3. The Commission is empowered to adopt implementing acts establishing ***common specifications that cover technical requirements providing a means to comply with*** the essential health and safety requirements set out in Annex III ***for products within the scope of this Regulation*** where the following conditions have been fulfilled:
 - (a) ***the Commission has requested, pursuant to Article 10(1) of Regulation No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and the request has not been accepted or the European standardisation deliverables addressing that request is not delivered within the deadline set in accordance with Article 10(1) of Regulation No 1025/2012 or European standardisation deliverables does not comply with the request; and***

- (b) ***no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).

- 3a. ***Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 that it considers that the conditions in paragraph 3 are fulfilled.***
- 3b. ***When preparing the draft implementing act establishing the common specification, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.***
4. ***A product within the scope of this Regulation which is in conformity with the common specifications established by one or more implementing acts referred to in paragraph 3 or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof.***
- 4a. ***Where a harmonised standard is adopted by an European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements set out in Annex III.***
- 4b. ***When a Member State considers that a common specification does not entirely satisfy the essential health and safety requirements set out in Annex III, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, may amend the implementing act establishing the common specification in question.***

5. Machinery **and related** products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU) 2019/881 and the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.

Article 18

EU declaration of conformity of **machinery and related products**

1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.
2. The EU declaration of conformity shall have the model structure set out in **part A of** Annex V, **and** shall contain the elements specified in the relevant modules set out in Annexes VI, **VIII, IX, and IXa** and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the machinery **or related** product is placed on the market, is made available on the market **or put into service**.
3. Where a machinery **or related** product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery **or related** product with the requirements laid down in this Regulation.

Article 18a

EU declaration of incorporation of partly completed machinery

- 1. The EU declaration of incorporation shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.***
- 2. The EU declaration of incorporation shall have the model structure set out in part B of Annex V. It shall be translated into the language or languages required by the Member State in which the partly completed machinery is placed on the market or is made available on the market.***
- 3. Where a partly completed machinery is subject to more than one Union act requiring an EU declaration of conformity, the EU declaration of incorporation shall include a sentence declaring the conformity with such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.***
- 4. By drawing up the EU declaration of incorporation, the manufacturer shall assume responsibility for the compliance of the partly completed machinery with the requirements laid down in this Regulation.***

Article 19
General principles of the CE marking

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

Article 20
Rules for affixing the CE marking *to machinery and related products*

1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery *or related* product. Where that is not possible or not warranted on account of the nature of the machinery *or related* product, it shall be affixed to the packaging and to the documents accompanying the machinery *or related* product.
2. The CE marking shall be affixed before the machinery *or related* product is placed on the market *or put into service*.
3. ***Where the conformity of machinery or related products is assessed in accordance with the conformity assessment procedure referred to in Article 21 (2) points a) and b) and c) and in article 21 (2a) points b) and c) and d) , the CE marking shall be followed by the identification number of the notified body involved in that procedure.***
The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.
4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or *any* other marking indicating a special risk or use.
5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER IV CONFORMITY ASSESSMENT

Article 21

Conformity assessment procedures for machinery *and related products*

1. ***The manufacturer or the natural or legal person referred to in Article 15 shall apply one of the procedures for assessment of conformity referred to in paragraphs 2, 2a and 3.***
2. Where the ***category of machinery or related product is*** listed in Annex I, ***part A***, the manufacturer or the ***natural or legal person referred to in Article 15*** shall apply one of the following procedures:
 - (a) EU type-examination procedure (module B) ***set out*** in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;
 - (b) conformity based on full quality assurance (module H) set out in Annex IX;
 - (c) ***conformity based on unit verification (module G) set out in Annex IXa.***
- 2a. ***Where the machinery or related product is listed in Annex I, part B, the manufacturer as defined in Article 3(17) and referred to in Article 15 shall apply one of the following procedures:***

- (a) *the internal production control procedure (module A) set out in Annex VI;*
- (b) *the EU type-examination procedure (module B) provided for in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;*
- (c) *conformity based on full quality assurance procedure (module H) set out in Annex IX;*
- (d) *conformity based on unit verification procedure (module G) set out in Annex IXa.*

If a manufacturer applies the internal production control procedure referred to in point (a), he or she shall have designed and constructed the machinery or related product in accordance with the harmonised standards or common specifications specific for that category of machinery or related product covering all the relevant essential health and safety requirements.

Where the machinery or related product is listed in Annex I part B and has not been manufactured in accordance with the harmonized standards or common specifications covering all the relevant essential health and safety requirements for that category of machinery or related product, the manufacturer shall apply one of the procedures referred to in paragraph 2a(b), (c) or (d).

3. Where the machinery *or related* product is not **■** listed in Annex I, the manufacturer or the *natural or legal* person *referred to in Article 15* shall apply the internal production control procedure (module A) set out in Annex VI.
4. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment **■** .

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 24 Notification

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

Article 25 Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article **30**.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 **■** to a body, which is not a governmental entity that body shall be a legal entity and shall comply *mutatis mutandis* **■** with the requirements laid down in Article 26. In addition, that body shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 26
Requirements relating to notifying authorities

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

Article 27
Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto. The Commission shall make that information publicly available.

Article 28
Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the machinery *or related* product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of machinery *or related* products which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a conformity assessment body.

4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, *importer, distributor*, installer, purchaser, owner, user or maintainer of **█** machinery *or related products*, that they assess, nor *fulfil any of those roles in relation to partly completed machinery that has been incorporated into the assessed product or be* the representative of any of those parties. This shall not preclude the use of *assessed* machinery *or related products that are* necessary for the operations of the conformity assessment body or the use of *machinery or related products* for personal purposes.

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

A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

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

At all times, and for each conformity assessment procedure and each kind of **■** machinery *or related products* for which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment *tasks*;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;
- (c) appropriate policies and procedures to distinguish between *tasks* that it carries out as a notified body and other activities;
- (d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.

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

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:
- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex III, of the applicable harmonised standards *and common specifications* referred to in Article 17, and of the relevant provisions of Union harmonisation legislation and of national legislation;
 - (d) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.
8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment *tasks* shall be guaranteed.
- The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment *tasks* shall not depend on the number of conformity assessments carried out or on the results of those assessments.

9. A conformity assessment body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment *tasks* in accordance with Annexes VII, *IX and IXa*, except in relation to the competent authorities of the Member State in which its *tasks* are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.
11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment *tasks* are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 29
Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 28 in so far as the applicable harmonised standards cover those requirements.

Article 30
Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 28 and shall inform the notifying authority accordingly.
2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes VII, *IX and IXa*.

Article 31
Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annexes VII, ***IX and IXa*** and of the ***kinds or categories*** of machinery ***or related products*** for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 28.

Article 32
Notification procedure

1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 28.
2. The notifying authority shall send a notification to the Commission and the other Member States █, using the electronic notification tool developed and managed by the Commission.
3. The notification referred to in paragraph 2 shall include the following:
 - (a) full details of the conformity assessment activities to be performed;
 - (b) an indication of the conformity assessment module or modules and the kinds of machinery *or related* products concerned;
 - (c) the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 28.
5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3) *and in paragraph 4 of this Article*.
Only such a body shall be considered a notified body for the purposes of this Regulation.
6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.

Article 33
Identification numbers and lists of notified bodies

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

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

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

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

Article 34
Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 28, or that it is failing to fulfil its obligations as set out in Article 36 the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 35
Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
2. The notifying *Member State* shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying *Member State* to take the necessary corrective measures, including the withdrawal of the notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

Article 36
Operational obligations of notified bodies

1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Annexes VII, ***IX and IXa***.
2. A notified body shall perform its activities in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the **■** technology in question and the mass or serial nature of the production process.

In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the machinery ***or related*** product with the requirements of this Regulation.

3. Where a notified body finds that the essential health and safety requirements set out in Annex III, or ***corresponding*** harmonised standards ***or common specifications*** referred to in Article 17 **■** have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective ***actions*** and shall not issue a certificate of conformity or adopt an approval decision.
4. Where, in the course of the monitoring of conformity following the ***issue of an approval decision according to Annex IX***, a notified body finds that a machinery ***or related*** product no longer complies, it shall require the manufacturer to take appropriate corrective ***actions*** and shall suspend or withdraw **■** the approval decision, if necessary.
5. Where corrective ***actions*** are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates **■** or approval decisions, as appropriate.

Article 37
Appeals against decisions of notified bodies

A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available.

Article 38
Information obligation on notified bodies

1. A notified body shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of a certificate  or approval decision;
 - (b) any circumstances affecting the scope of, or the conditions for, its notification;
 - (c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;
 - (d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.
2. A notified body shall provide *the other bodies notified under this Regulation* carrying out similar conformity assessment activities covering the same kinds of machinery *or related products* with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 39
Exchange of experience

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

Article 40
Coordination of notified bodies

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

■ Notified **bodies** shall participate in the work of that group, directly or by means of designated representatives.

CHAPTER VI

UNION MARKET SURVEILLANCE AND UNION SAFEGUARD PROCEDURES

Article 41

Procedure at national level for dealing with products presenting a risk

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a ***product within the scope of this Regulation*** presents a risk to the health or safety of persons, and, where appropriate, domestic animals or to property and, where applicable, the environment, they shall carry out an evaluation in relation to the product concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the ***product within the scope of this Regulation*** does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take appropriate ***and proportionate*** corrective action, ***as provided for in Article 16(3) of Regulation (EU) 2019/1020, to bring the non-compliance to an end*** or to ***eliminate hazards or, if that is not possible, minimize the risk they specify*** within a reasonable period which is commensurate with the nature of the risk referred to in the first subparagraph.

The market surveillance authorities shall inform the relevant notified body accordingly.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.
3. The economic operator shall ensure that all appropriate corrective action is taken in respect of *the concerned products within the scope of this Regulation* that the economic operator has made available on the market throughout the Union.
4. Where the relevant economic operator does not take ■ corrective action *referred to in paragraph 1, second subparagraph*, within the *specified* period *or where the non-compliance or the risk* referred to in paragraph 1, *first subparagraph*, *persists*, the market surveillance authorities shall *ensure that the product concerned is withdrawn or recalled, or that making available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly without delay.*
5. The information referred to in paragraph 4 ■ shall include all available details, in particular the data necessary for the identification of the non-compliant *product within the scope of this Regulation*, the origin of that ■ product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:
 - (a) failure of the ■ product to meet the requirements relating to the essential health and safety requirements set out in Annex III;
 - (b) shortcomings in the harmonised standards referred to in Article 17(1);
 - (c) shortcomings in the *common* specifications referred to in Article 17(4).

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the *concerned* product *within the scope of this Regulation*, and, in the event of disagreement with the adopted national measure, of their objections.
7. Where, within three months of receipt of the information referred to in paragraph 4, **█** no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.
8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the **█** product **█**, are taken in respect of the *concerned* product *within the scope of this Regulation* without delay.

Article 42
Union safeguard procedure

1. Where, on completion of the procedure set out in Article **41(4), (6) and (7)** objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall without delay communicate it to them and to the relevant economic operator or operators.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).

2. If the national measure is considered justified, all Member States shall **ensure that appropriate restrictive measures, such as withdrawal, are taken in respect of** the non-compliant **product within the scope of this Regulation**, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the **product within the scope of this Regulation** is attributed to shortcomings in the harmonised standards or **common** specifications referred to in Article 41(5), points (b) and (c), of this Regulation, the Commission shall **respectively** apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 **or in Article 17(4b) of this Regulation**.

Article 43

Compliant products within the scope of this Regulation which present a risk

1. Where, having carried out an evaluation under Article 41(1), a Member State finds that although a **product within the scope of this Regulation** is in compliance with the essential health and safety requirements set out in Annex III, it **presents** a risk to the health and safety of persons and, where appropriate, domestic animals or to property and, where applicable, the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the **product concerned**, when placed on the market, no longer presents that risk, to withdraw **that product** or to recall it within a reasonable period which is commensurate with the nature of the risk.
2. The economic operator shall ensure that corrective action is taken in respect of all the **products concerned** that the economic operator has made available on the market throughout the Union.
3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the **product concerned**, the origin and the supply chain of **that product**, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not and, where necessary, order appropriate measures.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).

On duly justified imperative grounds of urgency relating to the protection of the health and safety of persons, the Commission shall adopt an immediately applicable implementing act in accordance with the procedure referred to in Article 46(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators.

Article 44
Formal non-compliance

1. Without prejudice to Article 41, where a Member State makes one of the following findings with regard to a machinery *or related* product, it shall require the relevant economic operator to put an end to the non-compliance concerned:
 - (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Regulation;
 - (b) the CE marking has not been affixed;
 - (c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 20(3) or has not been affixed;
 - (d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;
 - (e) the technical documentation is either not available or not complete;
 - (f) the information referred to in Article 10(6) or Article 12(3) is absent, false or incomplete;
 - (g) any other administrative requirement provided for in Article 10 or Article 12 is not fulfilled.

- 1a.** *Without prejudice to Article 41, where a Member State makes one of the following findings with regard to partly completed machinery, it shall require the relevant economic operator to put an end to the non-compliance concerned:*
- (a) the EU declaration of incorporation has not been drawn up or has not been drawn up correctly;*
 - (b) the technical documentation is either not available or not complete;*
 - (c) the information referred to in Article 10a(5) or Article 12a(3) is absent, false or incomplete;*
 - (d) any other administrative requirement provided for in Article 10a or Article 12a is not fulfilled.*
- 2.** Where the non-compliance referred to in paragraph 1 *and 1a* persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the *concerned* product *within the scope of this Regulation* being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER VII DELEGATED POWERS AND COMMITTEE PROCEDURE

Article 45 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 5(2), **5(5b)** and 6(2) shall be conferred on the Commission for a period of five years from ... [the date of entry into force of this Regulation]. 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. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

4. The delegation of powers referred to in Articles 5(2), **5(5b)** and 6(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 5(2), **5(5b)** and 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 46
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 reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
- (3a) *Where the committee delivers no opinion regarding the draft implementing act as referred to in Article 17(3), the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.***
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.
5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

CHAPTER VIII CONFIDENTIALITY AND PENALTIES

Article 47 Confidentiality

1. All parties shall respect the confidentiality of the following information and data obtained in carrying out their tasks in accordance with this Regulation:
 - (a) personal data;
 - (b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless disclosure is in the public interest.
2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the competent national authorities and between competent national authorities and the Commission shall not be disclosed without the prior agreement of the originating competent national authority.
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.
4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements ***when these agreements and arrangements ensure that any exchange of information is in accordance with applicable Union law.***

Article 48
Penalties

1. Member States shall lay down the rules on penalties applicable to infringements by economic operators 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 and may include criminal penalties for serious infringements.
2. Member States shall, ***by 39 months following the entry into force of this Regulation, notify the Commission of those rules and of those measures*** and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER IX TRANSITIONAL AND FINAL PROVISIONS

Article 49 Repeals

1. Directive 73/361/EEC is repealed.

References to the repealed Directive 73/361/EEC shall be construed as references to this Regulation.

2. Directive 2006/42/EC is repealed with effect from ... [42 months after the date of entry into force of this Regulation].

References to the repealed Directive 2006/42/EC shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex XI.

Article 50 Transitional provisions

1. Member States shall not ■ impede the making available on the market of *products* which *were* placed on the market in conformity with Directive 2006/42/EC before ... [the date of *application* of this Regulation]. However, Chapter VI of this Regulation shall apply, *as from ... [the date of entry into force of this Regulation]*, mutatis mutandis to such *products* instead of Article 11 of that Directive, including *products* for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC ■ .
2. EC type-examination certificates and approval decisions issued in accordance with Article 12 of Directive 2006/42/EC shall remain valid until ■ they expire ■ .

Article 51
Evaluation and review

1. By ... [**60** months after the date of entry into force of this Regulation] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.
2. Taking account of technical progress and practical experience gained in Member States as indicated in Article 5, the Commission shall in its report include an evaluation on the following aspects of this Regulation:
 - (a) the essential health and safety requirements set out in Annex III;
 - (b) the conformity assessment procedure applicable to *machinery or related* products listed in Annex I. ■

Where appropriate, the report shall be accompanied by a legislative proposal for amendment of the relevant provisions of this Regulation.

- 2a. *By ... [36 months after the date of entry into force of this Regulation] and every five years thereafter, the Commission shall submit a specific report on the assessment of Article 5(4) and (5) of this Regulation to the European Parliament and to the Council. The reports shall be made public.*

The Commission shall in its reports include the following:

- (a) a summary of data and information provided by Member States in accordance with Article 5(5) during the reporting period;*
- (b) an assessment of the list of categories of machinery or related products in Annex I in view of the criteria set out in Article 5(4).*

In the reports, the Commission shall assess the appropriateness and availability of sufficient and comparable data and information, and identify any shortcomings, necessary to ensure effective functioning and enforcement of Article 5.

Article 52
Entry into force and application

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 ... [42 months after the date of entry into force of this Regulation], ***with the exception of:***

- a) ***articles 24 to 40 , which shall apply from ... [6 months following the entry into force of this Regulation];***
- b) ***article 48(1) which shall apply from ... [39 months following the entry into force of this Regulation];***
- c) ***Article 5 (4b) and article 46 which shall apply from ... [the date of entry into force of this Regulation];***
- d) ***Article 5 (2) to (4c) and (5b) and articles 45 and 51(2a), which shall apply from ... [12 months following the entry into force of this Regulation].***

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

Done at Brussels,

For the European Parliament For the Council

ANNEX I

CATEGORIES OF MACHINERY OR RELATED PRODUCTS TO WHICH ONE OF THE PROCEDURES REFERRED TO IN ARTICLE 21 (2) AND (2A) SHALL BE APPLIED

Part A

Categories of machinery or related products to which the procedures referred to in Article 21 (2) shall be applied

- 14. Removable mechanical transmission devices including their guards.
- 15. Guards for removable mechanical transmission devices.
- 16. Vehicle servicing lifts.
- 18. Portable cartridge-operated fixing and other impact machinery.
- 24. ***Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.***
- 25. Machinery embedding ***systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only to those systems.***

Part B

Categories of machinery or related products to which one of the procedures referred to in Article 21 (2a) shall be applied:

- 1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:**
 - 1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;**
 - 1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;**
 - 1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;**
 - 1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.**
- 2. Hand-fed surface planing machinery for woodworking.**
- 3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.**

4. ***Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:***
 - 4.1. ***sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;***
 - 4.2. ***sawing machinery with blade(s) assembled on a carriage with reciprocating motion.***
5. ***Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.***
6. ***Hand-fed tenoning machinery with several tool holders for woodworking.***
7. ***Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.***
8. ***Portable chainsaws for woodworking.***
9. ***Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.***
10. ***Injection or compression plastics-moulding machinery with manual loading or unloading.***

11. *Injection or compression rubber-moulding machinery with manual loading or unloading.*
 12. *Machinery for underground working of the following types:*
 - 12.1. *locomotives and brake-vans;*
 - 12.2. *hydraulic-powered roof supports.*
 13. *Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.*
 17. *Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres*
 19. *Protective devices designed to detect the presence of persons.*
 20. *Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9 of Part A, 10 and 11 of Part B.*
 21. *Logic units to ensure safety functions.*
 22. *Roll-over protective structures (ROPS).*
 23. *Falling-object protective structures (FOPS).*
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ANNEX II

INDICATIVE LIST OF SAFETY COMPONENTS

1. Guards for removable mechanical transmission devices.
2. Protective devices designed to detect the presence of persons.
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of Annex I.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for the control of dangerous movements of machinery.
6. Extraction systems for machinery emissions.
7. Guards and protective devices designed to protect persons against moving parts involved in the process of the machinery.
8. Monitoring devices for loading and movement control in lifting machinery.
9. Restraint systems to keep persons in their seats.
10. Emergency stop devices.
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex III.

13. Systems and devices to reduce the emission of noise and vibrations.
14. Roll-over protective structures (ROPS).
15. Falling-object protective structures (FOPS).
16. Two-hand control devices.
17. The following components for machinery designed for lifting and/or lowering persons between different landings:
 - (a) devices for locking landing doors;
 - (b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
 - (c) overspeed limitation devices;
 - (d) energy-accumulating shock absorbers, non-linear or with damping of the return movement;
 - (e) energy-dissipating shock absorbers;
 - (f) safety devices fitted to jacks of hydraulic power circuits and used to prevent falls;
 - (g) safety switches containing electronic components.

18. Software ensuring safety functions ■ .

18a. *Safety components with fully or partially self-evolving behavior using machine learning approaches ensuring safety functions.*

19. Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, including pesticides, and filters for such filtration systems.

ANNEX III

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY **OR RELATED PRODUCTS**

A.

DEFINITIONS

For the purpose of this Annex:

- (a) *'hazard' means a potential source of injury or damage to health;*
- (b) *'danger zone' means any zone within and/or around a machinery or related product in which a person is subject to a risk to his or her health or safety;*
- (c) *'exposed person' means any person wholly or partially in a danger zone;*
- (d) *'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving a machinery or related product;*
- (e) *'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;*
- (f) *'guard' means a part of a machinery or related product used specifically to provide protection by means of a physical barrier;*
- (g) *'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;*
- (h) *'intended use' means the use of a machinery or related product in accordance with the information provided in the instructions for use;*
- (j) *'reasonably foreseeable misuse' means the use of a machinery or related product in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.*

B.

GENERAL PRINCIPLES

1. The manufacturer of a machinery **or related product** shall ensure that a risk assessment is carried out in order to determine the health and safety requirements, which apply to the machinery **or related** product. The machinery **or related** product shall then be designed and constructed to **eliminate hazards or, if that is not possible, to** minimise all relevant risks, taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to in the first subparagraph, the manufacturer **■** shall:

- (a) determine the limits of the machinery **or related** product, which include the intended use and any reasonably foreseeable misuse thereof;

■

- (c) identify the hazards that may be generated by the machinery **or related** product **and**

the associated hazardous situations;

- (d) estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence;
- (e) evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Regulation;

- (f) eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b);

The risk assessment and risk reduction shall include hazards that may be generated during the lifecycle of the machinery or related product that are foreseeable at the time of placing of the machinery or related product on the market as an intended evolution of its fully or partially self-evolving behaviour or logic as a result of the machinery or related product designed to operate with varying levels of autonomy. The risk assessment and risk reduction shall include risks resulting from interactions between machinery in order to achieve the same end that are arranged and controlled so that they function as an integral whole, thus forming a machinery as defined in Article 3, point 1(d).

2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery ***or related*** product in question when it is used under the conditions foreseen by the manufacturer or **■** in foreseeable abnormal situations. However, the principles of safety integration established in section 1.1.2 and the obligations concerning marking of machinery ***or related product*** referred to in ***section 1.7.3, and instructions for use referred to in section 1.7.4*** apply in all cases.

3. The essential health and safety requirements laid down in this Annex are mandatory; however, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery *or related* product shall, as far as possible, be designed and constructed with the purpose of approaching those objectives.
4. This Annex is organised into six chapters. The first chapter is of general scope and applicable to all machinery *or related product*. The other chapters refer to certain sorts of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When a machinery *or related* product is being designed, the requirements of the first chapter and the requirements of one or more of the other chapters shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles. Essential health and safety requirements for the protection of the environment are applicable only to the machinery *or related* product referred to in section 2.4.
5. ***These general principles shall apply to the risk assessment carried out by the manufacturer of partly completed machinery.***

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1. GENERAL REMARKS

1.1.1. *Applicability*

The obligations laid down by the essential health and safety requirements are applicable to partly completed machinery in as much those requirements are relevant.

The relevant requirements in relation to partly completed machinery do not cover the requirements that can only be fulfilled at the time of the incorporation of the partly completed machinery. However the principles of safety integration established in section 1.1.2 are applicable in all cases.



1.1.2. Principles of safety integration

- (a) A machinery *or related* product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery *or related* product including the phases of transport, assembly, dismantling, disabling and scrapping.

- (b) In selecting the most appropriate methods, the manufacturer ■ shall apply the following principles, in the order given:
- (i) eliminate *hazards or, if that is not possible, minimise risks* (inherently safe machinery *or related* product design and construction);
 - (ii) take the necessary protective measures in relation to risks that cannot be eliminated;
 - (iii) inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.
- (c) When designing and constructing a machinery *or related* product and when drafting the instructions *for use*, the manufacturer ■ shall envisage not only the intended use of the machinery *or related* product but also any reasonably foreseeable misuse thereof. The machinery *or related* product shall be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions *for use* shall draw the user's attention to ways — which experience has shown might occur — in which the machinery *or related* product should not be used.

- (d) A machinery *or related* product shall be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.
- (e) A machinery *or related* product shall be designed and constructed in such a way that it is possible for the user, *where applicable*, to test the safety functions. The machinery *or related* product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.

1.1.3. Materials and products

The materials used to construct a machinery *or related* product, or products used or created during its use, shall not endanger persons' safety or health. In particular, where fluids are used, machinery *or related product* shall be designed and constructed to prevent risks due to filling, use, recovery or draining.

1.1.4. Lighting

A machinery *or related* product shall be supplied with integral lighting suitable for the operations concerned, where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.

A machinery *or related* product shall be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.

Internal parts requiring frequent inspection and adjustment, and maintenance areas shall be provided with appropriate lighting.

1.1.5. Design of a machinery *or related* product to facilitate its handling

A machinery *or related* product or each component part thereof, shall:

- (a) be capable of being handled and transported safely;
- (b) be packaged or designed so that it can be stored safely and without damage.

During the transportation of the machinery *or related* product *or* its component parts, there shall be no possibility of sudden movements or of hazards due to instability as long as the machinery *or related* product *or* its component parts are handled in accordance with the instructions.

Where the weight, size or shape of a machinery *or related* product or its various component parts prevents it or them from being moved by hand, the machinery *or related* product or each component part shall:

- (a) either be fitted with attachments for lifting gear; or
- (b) be designed so that it can be fitted with such attachments; or
- (c) be shaped in such a way that standard lifting gear can easily be attached.

Where a machinery *or related* product or one of its component parts is to be moved by hand, it shall either:

- (a) be easily moveable; or
- (b) be equipped for picking up and moving safely.

Special arrangements shall be made for the handling of tools and/or machinery *or related* product parts, which, even if lightweight, could be hazardous.

1.1.6. Ergonomics

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator shall be *eliminated or* reduced to the minimum possible, taking into account *at least, the following ergonomic principles*:

- (a) allowing for the variability of the operator's physical dimensions, strength and stamina;
- (aa) avoiding the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity;*
- (b) providing enough space for movements of the parts of the operator's body;
- (c) avoiding a machine-determined work rate;
- (d) avoiding monitoring that requires lengthy concentration;

- (e) adapting the *human-machine* interface to the foreseeable characteristics of the operators, including with respect to a machinery *or related* product with intended fully or partially *self-evolving* behaviour or logic that is designed to operate with varying levels of autonomy;
- (f) *where relevant*, adapting a machinery *or related* product with intended fully or partially *self-evolving* behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (*such as* verbally through words and non-verbally through gestures, facial expressions or body movement) and to communicate its planned actions (*such as* what it is going to do and why) to operators in a comprehensible manner.

1.1.7. Operating positions

The operating position shall be designed and constructed in such a way as to avoid any risk due to exhaust gases *or* lack of oxygen.

If the machinery *or related* product is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery *or related* product itself gives rise to a hazardous environment, adequate means shall be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position shall be fitted with an adequate cabin designed, constructed *or* equipped to fulfil the above requirements. The exit shall allow rapid evacuation. Moreover, when applicable, an emergency exit shall be provided in a direction which is different from the usual exit.

1.1.8. Seating

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery *or related* product shall be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery *or related* product, the seat shall be provided with the machinery *or related* product.

The operator's seat shall enable him *or her* to maintain a stable position. Furthermore, the seat and its distance from the control devices shall be capable of being adapted to the operator.

If the machinery *or related* product is subject to vibrations, the seat shall be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings shall withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material shall be provided.

1.1.9. Protection against corruption

The machinery *or related* product shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery *or related* product does not lead to a hazardous situation.

A hardware component *transmitting signal or data, relevant* for connection *or access to software* that is critical for the compliance of the machinery *or related* product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery *or related* product shall collect evidence of a legitimate or illegitimate intervention in *that* hardware component, *when relevant for connection or access to software that is critical for the compliance of the machinery or related product*.

Software and data that are critical for the compliance of the machinery *or related* product with the relevant health and safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.

The machinery *or related* product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.

The machinery *or related* product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery *or related* product or its configuration.

1.2. CONTROL SYSTEMS

1.2.1. Safety and reliability of control systems

Control systems shall be designed and constructed in such a way as to prevent hazardous situations from arising.

Control systems shall be designed and constructed in such a way that:

- (a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including *reasonably foreseeable* malicious attempts from third parties *leading to* a hazardous situation;
- (b) a fault in the hardware or the logic of the control system shall not lead to hazardous situations;
- (c) errors in the control system logic shall not lead to hazardous situations;
- (d) **■** the limits of the safety functions shall be *established as* part of the risk assessment performed by the manufacturer. *In this respect no modification is allowed* to the settings or rules generated by the machinery *or related* product or by operators, *including during the machinery or related product* learning phase, *where such modifications may lead to hazardous situations*;
- (e) reasonably foreseeable human errors during operation shall not lead to hazardous situations;
- (f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery *or related* product has been placed on the market or put into service, is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery *or related* product with this Annex further to a reasoned request from a competent national authority.

■

Control systems of machinery *or related product* with fully or partially *self-evolving* behaviour or logic that is designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:

- (a) they shall not cause the machinery *or related* product to perform actions beyond its defined task and movement space;
- (aa) ***recording of data on the safety related decision-making process for software based safety systems ensuring safety function including safety components, after the machinery or related product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority;***
- (b) it shall be possible at all times to correct the machinery *or related* product in order to maintain its inherent safety.

(iii) Particular attention shall be given to the following points:

- (a) the machinery *or related* product shall not start unexpectedly;
- (b) the parameters of the machinery *or related* product shall not change in an uncontrolled way, where such change may lead to hazardous situations;
- (c) modifications to the settings or rules, generated by the machinery *or related* product or by operators, ***including during the machinery or related product*** learning phase, shall be prevented, where such modifications may lead to hazardous situations;

- (d) the machinery *or related* product shall not be prevented from stopping if the stop command has already been given;
- (e) no moving part of the machinery *or related* product or piece held by the machinery *or related* product shall fall or be ejected;
- (f) automatic or manual stopping of the moving parts, whatever they may be, shall be unimpeded;
- (g) the protective devices shall remain fully effective or give a stop command;
- (h) the safety-related parts of the control system shall apply in a coherent way to the whole of an assembly of a machinery *or related* product.

For wireless control, a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation.



1.2.2. Control devices

Control devices shall be:

- (a) clearly visible and identifiable, using pictograms where appropriate;
- (b) positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity;
- (c) designed in such a way that the movement of the control device is consistent with its effect;

- (d) located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant;
- (e) positioned in such a way that their operation cannot cause additional risk;
- (f) designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action;
- (g) made in such a way as to withstand foreseeable forces, paying particular attention to emergency stop devices liable to be subjected to considerable forces.

Where a control device is designed and constructed to perform several different actions, namely, where there is no one-to-one correspondence, the action to be performed shall be clearly displayed and subject to confirmation, where necessary.

Control devices shall be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

Machinery *or related* products shall be fitted with indicators as required for safe operation. The operator shall be able to read them from the control position.

From each control position, the operator shall be able to ensure that no one is in the danger zones, or the control system shall be designed and constructed in such a way that starting is prevented while someone is in the danger zone.

If neither of these possibilities is applicable, before the machinery *or related* product starts, an acoustic and/or visual warning signal shall be given. The exposed persons shall have time to leave the danger zone or prevent the machinery starting up.

If necessary, means shall be provided to ensure that the machinery *or related* product can be controlled only from control positions located in one or more predetermined zones or locations.

Where there is more than one control position, the control system shall be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When the machinery *or related* product has two or more operating positions, each position shall be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.

1.2.3. Starting

It shall be possible to start the machinery *or related* product only by voluntary actuation of a control device provided for the purpose.

The same requirement applies:

- (a) when restarting the machinery *or related* product after a stoppage, whatever the cause;
- (b) when effecting a significant change in the operating conditions.

However, the restarting of the machinery *or related* product or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.

For the machinery *or related* product functioning in automatic mode, the starting of the machinery *or related* product, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.

Where the machinery *or related* product has several starting control devices and the operators can therefore put each other in danger, additional devices shall be fitted to rule out such risks. If safety requires that starting and/or stopping shall be performed in a specific sequence, there shall be devices that ensure that these operations are performed in the correct order.

1.2.4. Stopping

1.2.4.1. Normal stop

The machinery *or related* product shall be fitted with a control device whereby the machinery can be brought safely to a complete stop.

Each workstation shall be fitted with a control device to stop some or all of the functions of the machinery *or related* product, depending on the existing hazards, so that the machinery *or related* product is rendered safe.

The machinery *or related* product's stop control shall have priority over the start controls.

Once the machinery *or related* product or its hazardous functions have stopped, the energy supply to the actuators concerned shall be cut off.

1.2.4.2. Operational stop

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition shall be monitored and maintained.

1.2.4.3. Emergency stop

The machinery *or related* product shall be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.

The following exceptions apply:

- (a) the machinery *or related* product in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken;
- (b) portable hand-held and/or hand-guided machinery *or related* product.

The device shall:

- (a) have clearly identifiable, clearly visible and quickly accessible control devices;
- (b) stop the hazardous process as quickly as possible, without creating additional risks;
- (c) where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop device has ceased following a stop command, that command shall be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it shall not be possible to engage the device without triggering a stop command; it shall be possible to disengage the device only by an appropriate operation, and disengaging the device shall not restart the machinery *or related* product but only permit restarting.

The emergency stop function shall be available and operational at all times, regardless of the operating mode.

Emergency stop devices shall be a backup to other safeguarding measures and not a substitute for them.

1.2.4.4. Assembly of machinery *or related* products

In the case of a machinery *or related products* or parts of a machinery *or related products* designed to work together, the machinery shall be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery *or related products* itself but also all related equipment, if its continued operation may be dangerous.

1.2.5. Selection of control or operating modes

The control or operating mode selected shall override all other control or operating modes, with the exception of the emergency stop.

If the machinery *or related* product has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it shall be fitted with a mode selector, which can be locked in each position. Each position of the selector shall be clearly identifiable and shall correspond to a single operating or control mode.

The selector may be replaced by another selection method, which restricts the use of certain functions of the machinery *or related* product to certain categories of operator.

If, for certain operations, the machinery shall be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector shall simultaneously:

- (a) disable all other control or operating modes;
- (b) permit operation of hazardous functions only by control devices requiring sustained action;
- (c) permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences;
- (d) prevent any operation of hazardous functions by voluntary or involuntary action on the machine product's sensors.

If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector shall activate other protective measures designed and constructed to ensure a safe intervention zone.

In addition, the operator shall be able to control the operation of the parts he or she is working on from the adjustment point.

1.2.6. Failure of the power supply or communication network connection

The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply or communication network connection to the machinery *or related* product shall not lead to hazardous situations.

Particular attention shall be given to the following:

- (a) the machinery *or related products* shall not start unexpectedly;
- (b) the parameters of the machinery shall not change in an uncontrolled way when such change can lead to hazardous situations;
- (c) the machinery *or related products* shall not be prevented from stopping if the stop command has already been given;
- (d) no moving part of the machinery *or related products* or piece held by the machinery *or related products* shall fall or be ejected;
- (e) automatic or manual stopping of the moving parts, whatever they may be, shall be unimpeded;
- (f) the protective devices shall remain fully effective or give a stop command.

1.3. PROTECTION AGAINST MECHANICAL RISKS

1.3.1. Risk of loss of stability

The machinery *or related* product and its components and fittings shall be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery *or related products*.

If the shape of the machinery *or related products* itself or its intended installation does not offer sufficient stability, appropriate means of anchorage shall be incorporated and indicated in the instructions *for use*.

1.3.2. Risk of break-up during operation

The various parts of machinery *or related* product and their linkages shall be able to withstand the stresses to which they are subject when used.

The durability of the materials used shall be adequate for the nature of the working environment foreseen by the manufacturer **■**, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

The instructions *for use* shall indicate the type and frequency of inspections and maintenance required for safety reasons. They shall, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned shall be mounted, positioned *or* guarded in such a way that any fragments will be contained, preventing hazardous situations.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, shall be able to withstand the foreseen internal and external stresses and shall be firmly attached *or* protected to ensure that no risk is *presented* by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions shall be fulfilled to avoid risks to persons:

- (a) when the work piece comes into contact with the tool, the latter shall have attained its normal working condition;
- (b) when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement shall be coordinated.

1.3.3. Risks due to falling or ejected objects

Precautions shall be taken to prevent risks from falling or ejected objects.

1.3.4. Risks due to surfaces, edges or angles

Insofar as their purpose allows, accessible parts of the machinery shall have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

1.3.5. Risks related to a combined machinery *or related* product

Where the machinery *or related* product is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery *or related* product), it shall be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.

For this purpose, it shall be possible to start and stop separately any elements that are not protected.

1.3.6. Risks related to variations in operating conditions

Where the machinery *or related* product performs operations under different conditions of use, it shall be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. Risks related to moving parts ■

The moving parts of the machinery *or related* product shall be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or shall, where risks persist, be fitted with guards or protective devices.

All necessary steps shall be taken to prevent accidental blockage of moving parts. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools shall, when appropriate, be provided to enable the equipment to be safely unblocked.

The instructions *for use* and, where possible, a sign on the machinery *or related* product shall identify these specific protective devices and how they are to be used.

The prevention of risks of contact leading to hazard situations and the psychological stress that may be caused by the interaction with the machine shall be adapted to:

- (a) human-machine coexistence in a shared space without direct collaboration;
- (b) human-machine interaction.



1.3.8. Choice of protection against risks arising from moving parts

Guards or protective devices designed to protect against risks arising from moving parts shall be selected on the basis of the type of risk. The following guidelines shall be used to help to make the choice.

1.3.8.1. Moving transmission parts

Guards designed to protect persons against the hazards generated by moving transmission parts shall be:

- (a) either fixed guards as referred to in section 1.4.2.1; or
- (b) interlocking movable guards as referred to in section 1.4.2.2.

Interlocking movable guards shall be used where frequent access is envisaged.

1.3.8.2. Moving parts involved in the process

Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process shall be:

- (a) either fixed guards as referred to in section 1.4.2.1; or
- (b) interlocking movable guards as referred to in section 1.4.2.2; or
- (c) protective devices as referred to in section 1.4.3; or
- (d) a combination of the above.

However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts shall be fitted with:

- (a) fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work; and
- (b) adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.

1.3.9. Risks of uncontrolled movements

When a part of the machinery *or related* product has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, shall be prevented or shall be such that it does not present a risk.

1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES

1.4.1. General requirements

Guards and protective devices shall:

- (a) be of robust construction;
- (b) be securely held in place;
- (c) not give rise to any additional hazard;
- (d) not be easy to by-pass or render non-operational;
- (e) be located at an adequate distance from the danger zone;
- (f) cause minimum obstruction to the view of the production process, and;
- (g) enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.

In addition, guards shall, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery *or related* product.

1.4.2. Special requirements for guards

1.4.2.1. Fixed guards

Fixed guards shall be fixed by systems that can be opened or removed only with tools.

Their fixing systems shall remain attached to the guards or to the machinery *or related* product when the guards are removed.

Where possible, guards shall be incapable of remaining in place without their fixings.

1.4.2.2. Interlocking movable guards

Interlocking movable guards shall:

- (a) as far as possible remain attached to the machinery *or related* product when open;
- (b) be designed and constructed in such a way that they can be adjusted only by means of an intentional action.

Interlocking movable guards shall be associated with an interlocking device that:

- (a) prevents the start of hazardous machinery *or related* product functions until they are closed; and
- (b) gives a stop command whenever they are no longer closed.

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery *or related* product functions has ceased, movable guards shall be associated with a guard locking device in addition to an interlocking device that:

- (a) prevents the start of hazardous machinery *or related* product functions until the guard is closed and locked; and
- (b) keeps the guard closed and locked until the risk of injury from the hazardous machinery *or related* product functions has ceased.

Interlocking movable guards shall be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery *or related* product functions.

1.4.2.3. Adjustable guards restricting access

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work shall be:

- (a) adjustable manually or automatically, depending on the type of work involved; and
- (b) readily adjustable without the use of tools.

1.4.3. Special requirements for protective devices

Protective devices shall be designed and incorporated into the control system in such a way that:

- (a) moving parts cannot start up while they are within the operator's reach;

- (b) persons cannot reach moving parts while the parts are moving, and
- (c) the absence or failure of one of their components prevents starting or stops the moving parts.

Protective devices shall be adjustable only by means of an intentional action.

1.5. RISKS DUE TO OTHER CAUSES

1.5.1. Electricity supply

Where a machinery *or related* product has an electricity supply, it shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.

The safety objectives set out in Directive 2014/35/EU shall apply to a machinery *or related* product. However, the obligations concerning conformity assessment and the placing on the market *or* putting into service of a machinery *or related* product with regard to electrical risks are governed solely by this Regulation.

1.5.2. Static electricity

A machinery *or related* product shall be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3. Energy supply other than electricity

Where a machinery *or related* product is powered by source of energy other than electricity, it shall be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.

1.5.4. Errors of fitting

Errors likely to be made when fitting or refitting certain parts, which could be a source of risk, shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves *or* their housings. The same information shall be given on moving parts *or* their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions *for use* shall give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections shall be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.

1.5.5. Extreme temperatures

Steps shall be taken to eliminate any risk of injury arising from contact with or proximity to machinery *or related* product parts or materials at high or very low temperatures.

The necessary steps shall also be taken to avoid or protect against the risk of hot or very cold material being ejected.

1.5.6. Fire

A machinery *or related* product shall be designed and constructed in such a way as to avoid any risk of fire or overheating *presented* by the machinery *or related* product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery *or related* product.

1.5.7. Explosion

A machinery *or related* product shall be designed and constructed in such a way as to avoid any risk of explosion *presented* by the machinery *or related* product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery *or related* product.

A machinery *or related* product shall comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Union harmonisation legislation.

1.5.8. Noise

A machinery *or related* product shall be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.

The level of noise emission may be assessed with reference to comparative emission data for similar machinery *or related* product.

1.5.9. Vibrations

A machinery *or related* product shall be designed and constructed in such a way that risks resulting from vibrations produced by the machinery *or related* product are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

The level of vibration emission may be assessed with reference to comparative emission data for similar machinery *or related* products.

1.5.10. Radiation

Undesirable radiation emissions from the machinery *or related* product shall be eliminated or be reduced to levels that do not have adverse effects on persons.

Any functional ionising radiation emissions shall be limited to the lowest level, which is sufficient for the proper functioning of the machinery *or related* product during setting, operation and cleaning. Where a risk exists, the necessary protective measures shall be taken.

Any functional non-ionising radiation emissions during setting, operation and cleaning shall be limited to levels that do not have adverse effects on persons.

1.5.11. External radiation

A machinery *or related* product shall be designed and constructed in such a way that external radiation does not interfere with its operation.

1.5.12. Laser radiation

Where laser equipment is used, the following shall be taken into account:

- (a) laser equipment on a machinery *or related* product shall be designed and constructed in such a way as to prevent any accidental radiation;
- (b) laser equipment on a machinery *or related* product shall be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health;

- (c) optical equipment for the observation or adjustment of laser equipment on a machinery *or related* product shall be such that no health risk is created by laser radiation.

1.5.13. Emissions of hazardous materials and substances

A machinery *or related* product shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a risk cannot be eliminated, the machinery *or related* product shall be so equipped that hazardous materials and substances can be contained, captured, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery *or related* product, the devices for containment or capture, filtration or separation and evacuation shall be situated in such a way as to have the maximum effect.

1.5.14. Risk of being trapped in a machine

A machinery *or related products* shall be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.

1.5.15. Risk of slipping, tripping or falling

Parts of the machinery *or related products* where persons are liable to move about or stand shall be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.

Where appropriate, these parts shall be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

1.5.16. Lightning

A machinery *or related* product in need of protection against the effects of lightning while being used shall be fitted with a system for conducting the resultant electrical charge to earth.

1.6. MAINTENANCE

1.6.1. Machinery *or related* product maintenance

Adjustment and maintenance points shall be located outside danger zones. It shall be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while the machinery *or related* product is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, measures shall be taken to ensure that these operations can be carried out safely (see section 1.2.5).

In the case of automated machinery and, where necessary, other machinery *or related* product, a connecting device for mounting diagnostic fault-finding equipment shall be provided.

Automated machinery components, which have to be changed frequently, shall be capable of being removed and replaced easily and safely. Access to the components shall enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.

1.6.2. Access to operating positions and servicing points

Machinery shall be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, maintenance and cleaning of the machinery.

In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be dimensioned and adapted for the use of rescue equipment in such a way that a **emergency** rescue of the persons is **possible**.

1.6.3. Isolation of energy sources

A machinery **or related** product shall be fitted with means to isolate it from all energy sources. Such isolators shall be clearly identified. They shall be capable of being locked if reconnection could endanger persons. Isolators shall also be capable of being locked where an operator is unable, from any of the points to which he or she has access, to check that the energy is still cut off.

In the case of machinery **or related** products capable of being plugged into an electricity supply, removal of the plug is sufficient, if the operator can check from any of the points to which he or she has access that the plug remains removed.

After the energy is cut off, it shall be possible to dissipate normally any energy remaining or stored in the circuits of the machinery *or related* product without risk to persons.

As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps shall be taken to ensure operator safety.

1.6.4. Operator intervention

The machinery *or related* product shall be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it shall be possible to carry it out easily and safely.

1.6.5. Cleaning of internal parts

The machinery shall be designed and constructed in such a way that it is possible to clean internal parts, which have contained dangerous substances or preparations without entering them; any necessary unblocking shall also be possible from the outside. If it is impossible to avoid entering the machinery, it shall be designed and constructed in such a way as to allow cleaning to take place safely.

1.7. INFORMATION

1.7.1. Information and warnings on the machinery *or related* product

Information and warnings on the machinery *or related* product shall preferably be provided in the form of readily understandable symbols or pictograms.

Any written or verbal information and warnings must be expressed in a language which can be easily understood by users, as determined by the Member State concerned.

1.7.1.1. Information and information devices

The information needed to control a machinery ***or related*** product shall be provided in a form that is unambiguous and easily understood. It shall not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the machinery ***or related*** product shall be easily understood and easy to use.

1.7.1.2. Warning devices

Where the health and safety of persons may be endangered by a fault in the operation of an unsupervised machinery ***or related*** product, the machinery ***or related*** product shall be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where a machinery ***or related*** product is equipped with warning devices, these shall be unambiguous and easily perceived. The operator shall have facilities to check the operation of such warning devices at all times.

The requirements of the specific Union legislation concerning colours and safety signals shall be complied with.

1.7.2. Warning of residual risks

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, shall be provided.

1.7.3. Marking of a machinery *or related* product

In addition to the marking requirements in Article 10 and 20, machinery *or related* products shall be marked visibly, legibly and indelibly.

Products covered by Annex III points 2 to 6 shall also be marked according to the additional requirements set out in these sections.

Furthermore, a machinery *or related* product designed and constructed for use in a potentially explosive atmosphere shall be marked accordingly.

A machinery *or related* product shall also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.

Where a *machinery or related* product part shall be handled during use with lifting equipment, its mass shall be indicated legibly, indelibly and unambiguously.

1.7.4. Instructions *for use*

In addition to the obligations set out in Article 10(7), instructions shall be drawn up as follows.

By way of exception *from Article 10(7)*, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his or her authorised representative may be supplied in only one official language of the Union which the specialised personnel understand.



1.7.4.1. General principles for the drafting of instructions *for use*



- (c) The contents of the instructions *for use* shall cover not only the intended use of the machinery *or related* product but also take into account any reasonably foreseeable misuse thereof;
- (d) In the case of a machinery *or related* product intended for use by non-professional operators, the wording and layout of the instructions for use shall take into account the level of general education and acumen that can reasonably be expected from such operators.



1.7.4.2. Contents of the instructions *for use*

1. *Instructions for use* shall contain, where applicable, at least the following information:

- (a) the business name and full address of the manufacturer and, where applicable, of his or her authorised representative;

- (b) the designation of the machinery *or related* product as marked on the machinery *or related* product itself, except for the serial number (see section 1.7.3);
- (c) the EU declaration of conformity, or *the internet address or machine readable code*, where the EU declaration of conformity can be accessed, *in accordance with Article 10(8)*;
- (d) a general description of the machinery *or related* product;
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery *or related* product and for checking its correct functioning;
- (f) a description of the workstation(s) likely to be occupied by operators;
- (g) a description of the intended use of the machinery *or related* product;
- (h) warnings concerning ways in which the machinery *or related* product shall not be used that experience has shown might occur;
- (i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery *or related* product is to be mounted;
- (j) instructions relating to installation and assembly for reducing noise or vibration;
- (k) instructions for the putting into service and use of the machinery *or related* product and, if necessary, instructions for the training of operators;
- (l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;

- (m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;
- (n) the essential characteristics of tools, which may be fitted to the machinery *or related* product;
- (o) the conditions in which the machinery *or related* product meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
- (p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery *or related* product and of its various parts where these are regularly to be transported separately;
- (q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;
- (r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the design and the use of the machinery *or related* product;
- (s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- (t) the specifications of the spare parts to be used, when these affect the health and safety of operators;

- (u) the following information on airborne noise emissions:
- (i) the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB (A); where this level does not exceed 70 dB (A), this fact shall be indicated;
 - (ii) the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μ Pa);
 - (ii) the A-weighted sound power level emitted by the machinery *or related* product, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).

These values shall be either those actually measured for the machinery *or related* product in question or those established on the basis of measurements taken for a technically comparable machinery *or related* product, which is representative of the machinery *or related* product to be produced.

In the case of a very large machinery *or related* product, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery *or related* product may be indicated.

Where the harmonised standards or *common* specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, sound levels shall be measured using the most appropriate method for the machinery *or related* product.

Whenever sound emission values are indicated, the uncertainties surrounding these values shall be specified. The operating conditions of the machinery *or related* product during measurement and the measuring methods used shall be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels shall be measured at a distance of 1 metre from the surface of the machinery *or related* product and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure shall be indicated.

With respect to noise reduction machinery *or related* products, the instructions *for use* shall specify, where appropriate, how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).

Where specific Union legislation lays down other requirements for the measurement of sound pressure levels or sound power levels, those legal acts shall be applied and the corresponding provisions of this section shall not apply;

- (ua) ***information on the necessary precautions, devices and means for the immediate and gentle rescue of persons;***
- (v) where a machinery *or related* product is likely to emit non-ionising radiation, which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons;

- (w) where the machinery *or related* product design allows emissions of hazardous substances from the machinery *or related* product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery *or related* product, and any of the following:
- (i) the flow rate for the emission of hazardous materials and substances from the machinery *or related* product;
 - (ii) the concentration of hazardous materials or substances around the machinery *or related* product coming from the machinery *or related* product or from materials or substances used with the machinery *or related* product;
 - (iii) the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time.

The values referred to in the first subparagraph shall either be actually measured for the machinery *or related* product in question or established based on measurements in respect of a technically comparable machinery *or related* product, which is representative of the state of the art.

1.7.5. Sales literature

Sales literature describing the machinery *or related* product shall not contradict the instructions *for use* as regards health and safety aspects. Sales literature describing the performance characteristics of *the machinery or related product* shall contain the same information on emissions as is contained in the instructions *for use*.

2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY *AND RELATED* PRODUCTS

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics and machinery for pesticide application shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

2.1. *MACHINERY AND RELATED PRODUCTS FOR* FOODSTUFFS *AND* MACHINERY *AND RELATED PRODUCTS* FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General

Machinery *or related product* intended for use with foodstuffs or with cosmetics or pharmaceutical products shall be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

The following requirements shall be observed:

- (a) materials in contact with, or intended to come into contact with, foodstuffs or *water intended for human consumption or* cosmetics or pharmaceutical products shall satisfy the conditions set down in the relevant Union legal acts. The machinery *or related product* shall be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible, disposable parts shall be used;

- (b) all surfaces in contact with foodstuffs *or water intended for human consumption* or cosmetics or pharmaceutical products, other than surfaces of disposable parts, shall:
 - (i) be smooth and have neither ridges nor crevices, which could harbour organic materials. The same applies to their joinings;
 - (ii) be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum;
 - (iii) be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces shall have curves with a radius sufficient to allow thorough cleaning;
- (c) it shall be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery *or related product* (if possible, in a 'cleaning' position);
- (d) machinery *or related product* shall be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;
- (e) machinery *or related product* shall be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery *or related product* shall be designed and constructed in such a way that continuing compliance with this requirement can be checked.

2.1.2. Instructions *for use*

The instructions for *use for* foodstuffs machinery *or related product* and machinery *or related product* for use with cosmetics or pharmaceutical products shall indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

2.2. PORTABLE HAND-HELD **OR** HAND-GUIDED MACHINERY **OR RELATED PRODUCTS**

2.2.1. General

Portable hand-held *or* hand-guided machinery *or related product* shall:

- (a) depending on the type of machinery *or related product*, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery *or related product* under the intended operating conditions;
- (b) except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles;
- (c) present no risks of accidental starting *or* continued operation after the operator has released the handles. Equivalent steps shall be taken if this requirement is not technically feasible;

- (d) permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed;
- (e) have a device or a connected exhaust system, with an extraction connection outlet or equivalent system to capture or reduce emissions of hazardous substances. This requirement does not apply *if it leads to* a new *hazard or* where the main function of the machinery *or related product* is the *application* of hazardous substances and to emissions of internal combustion engines ■ ;
- (f) ***be designed and constructed in such a way that the handles of portable machinery or related product make starting and stopping straightforward.***

2.2.1.1. Instructions *for use*

The instructions *for use* shall give the following information concerning vibrations, expressed as acceleration (m/s^2), and transmitted by portable handheld and hand-guided machinery *or related product*:

- (a) the vibration total value from continuous vibrations to which the hand-arm system is subjected;
- (b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;
- (c) the uncertainty of both measurements.

The values referred to in the first subparagraph shall either be those actually measured for the machinery *or related products* in question or those established on the basis of measurements in respect of a technically comparable machinery *or related* product, which is representative of the state of the art.

If harmonised standards or *common* specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, the vibration data shall be measured using the most appropriate measurement code for the machinery *or related products*.

The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, shall be specified.

2.2.2. Portable fixing and other impact machinery *or related products*

2.2.2.1. General

Portable fixing and other impact machinery *or related product* shall be designed and constructed in such a way that:

- (a) energy is transmitted to the impacted element by the intermediary component that does not leave the device;
- (b) an enabling device prevents impact unless the machinery *or related product* is positioned correctly with adequate pressure on the base material;
- (c) involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device shall be required to trigger an impact;

- (d) accidental triggering is prevented during handling or in case of shock;
- (e) loading and unloading operations can be carried out easily and safely.

Where necessary, it shall be possible to fit the device with splinter guard(s) and the appropriate guard(s) shall be provided by the manufacturer of the machinery *or related product*.

2.2.2.2. Instructions *for use*

The instructions *for use* shall give the necessary information regarding:

- (a) the accessories and interchangeable equipment that can be used with the machinery *or related product*,
- (b) the suitable fixing or other impacted elements to be used with the machinery *or related product*,
- (c) where appropriate, the suitable cartridges to be used.

2.3. MACHINERY **OR RELATED PRODUCTS** FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS

Machinery *or related product* for working wood and materials with similar physical characteristics shall comply with the following requirements:

- (a) the machinery *or related product* shall be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter shall be sufficiently stable during the work and shall not impede the movement of the piece;

- (b) where the machinery *or related product* is likely to be used in conditions involving the risk of ejection of work pieces or parts of them, it shall be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;
- (c) the machinery *or related product* shall be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;
- (d) where the tool is incorporated into a non-fully automated machine, the latter shall be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.

2.4. MACHINERY *OR RELATED PRODUCTS* FOR PLANT PROTECTION PRODUCTS APPLICATION

2.4.1. Definition

‘Machinery for plant protection products application’ means machinery *or related products* specifically intended for the application of plant protection products within the meaning of Article 2, point (1), of Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹⁸.

¹⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

2.4.2. General

The manufacturer of machinery *or related product for pesticide application* shall ensure that an assessment is carried out of the risks of unintended exposure of the environment to pesticides, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1.

Machinery *or related product* for pesticide application shall be designed and constructed taking into account the results of the risk assessment referred to in the first subparagraph so that the machinery *or related product* can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.

Leakage shall be prevented at all times.

2.4.3. Controls and monitoring

It shall be possible to easily and accurately control, monitor and immediately stop the pesticide application from the operating positions.

2.4.4. Filling and emptying

The machinery *or related product* shall be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of pesticide and avoiding the contamination of the water source during such operations.

2.4.5. Application of pesticides

2.4.5.1. Application rate

The machinery *or related product* shall be fitted with means of adjusting the application rate easily, accurately and reliably.

2.4.5.2. Distribution, deposition and drift of pesticide

The machinery *or related product* shall be designed and constructed to ensure that pesticide is deposited on target areas, to minimise losses to other areas and to prevent drift of pesticide to the environment. Where appropriate, an even distribution and homogeneous deposition shall be ensured.

2.4.5.3. Tests

In order to verify that the relevant parts of the machinery *or related product* comply with the requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer **■** shall, for each type of machinery *or related product* concerned, perform appropriate tests, or have such tests performed.

2.4.5.4. Losses during stoppage

The machinery *or related product* shall be designed and constructed to prevent losses while the pesticide application function is stopped.

2.4.6. Maintenance

2.4.6.1. Cleaning

The machinery *or related product* shall be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.

2.4.6.2. Servicing

The machinery *or related product* shall be designed and constructed to facilitate the changing of worn parts without contamination of the environment.

2.4.7. Inspections

It shall be possible to easily connect the necessary measuring instruments to the machinery *or related product* to check the correct functioning of the machinery *or related product*.

2.4.8. Marking of nozzles, strainers and filters

Nozzles, strainers and filters shall be marked so that their type and size can be clearly identified.

2.4.9. Indication of pesticide in use

Where appropriate, the machinery *or related product* shall be fitted with a specific mounting on which the operator can place the name of the pesticide in use.

2.4.10. Instructions *for use*

The instructions *for use* shall provide the following information:

- (a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment;

- (b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of pesticide on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide;
- (c) the range of types and sizes of nozzles, strainers and filters that can be used with the machinery *or related product*;
- (d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery *or related product*, such as nozzles, strainers and filters;
- (e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery *or related product*;
- (f) types of pesticides that may cause incorrect functioning of the machinery *or related product*;
- (g) an indication that the operator should keep updated the name of the pesticide in use on the specific mounting referred to in section 2.4.9;

- (h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken;
- (i) an indication that the machinery *or related product* may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council¹⁹;
- (j) the features of the machinery *or related product*, which shall be inspected to ensure its correct functioning;
- (k) instructions for connecting the necessary measuring instruments.

3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY **OR RELATED PRODUCTS**

Machinery *or related product* presenting risks due to its mobility shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

3.1. GENERAL

3.1.1. Definitions

- (a) ‘Machinery *or related product* presenting risks due to its mobility’ means:
 - (i) machinery *or related product*, the operation of which requires either mobility while working, or continuous or semi continuous movement between a succession of fixed working locations; or

¹⁹ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

- (ii) machinery *or related product* which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another;
- (b) ‘Driver’ means *an operator* responsible for the movement of a *machinery or related product*, who may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control ■ ;
- (c) ‘Autonomous mobile machinery’ means a mobile machinery that has an autonomous mode, in which all the essential safety functions of the mobile machinery are ensured in its travel and working operations area without permanent interaction of an operator;
- (ca) ‘*Supervisor*’ means *a person responsible for the supervision of an autonomous mobile machinery*;
- (cb) ‘*Supervisory function*’ means *remote non permanent surveillance of an autonomous mobile machinery by a device allowing to receive information or alerts and to give limited orders to this machinery*.

3.2. WORK POSITIONS

3.2.1. Driving position

Visibility from the driving position shall be such that the driver can, in complete safety for himself or herself and the exposed persons operate the machinery *or related product* and its tools in their foreseeable conditions of use. Where necessary, appropriate devices shall be provided to remedy risks due to inadequate direct vision.

Machinery *or related product* on which the driver is transported shall be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers shall be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab shall incorporate a place for the instructions *for use* needed for the driver.

3.2.2. Seating

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4:

- (a) the machinery shall be designed or equipped with a restraint system so as to keep the persons in their seats or in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. ■

Where there is a significant roll or tip over risk and its restraint system is not used it shall not be possible for the machinery to move.

Such restraint systems or provision shall take ergonomic principles into account and shall not be fitted if they increase the risk;

(b) a visual *and* audible signal shall be provided at the driving position alerting the driver when the *driver is in the driving position and not using the restraint system*.

3.2.3. Positions for other persons

If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions shall be provided which enable them to be transported or to work on it without risk.

The second and third subparagraphs of section 3.2.1 also apply to the places provided for persons other than the driver.

3.2.4. Supervisory ■ function

Where relevant, autonomous mobile machinery *or related* products shall have a supervisory ■ function specific to the autonomous mode. This function shall allow the *supervisor* to remotely receive information from the machine. The supervisory ■ function shall only allow actions to stop and to start remotely the *machinery or move it to a safe position and a safe state to avoid causing other risks*. It shall be designed and constructed to allow those actions only when the *supervisor* can see directly or indirectly the machine's movement and working area and the protective devices are operational.

The information the *supervisor* receives from the machine when the supervisory ■ function is active shall enable the *supervisor* to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.

This information shall alert the *supervisor* of the occurrence of unforeseen or dangerous situations present or impending, which require *supervisor's* intervention.

If the supervisory  function is not active, the machinery shall not be able to operate.

3.3. CONTROL SYSTEMS

If necessary, steps shall be taken to prevent unauthorised use of controls.

In the case of remote controls, each control unit shall clearly identify the machinery *or related product* to be controlled from that unit.

The remote control system shall be designed and constructed in such a way as to affect only:

- (a) the machinery *or related product* in question;
- (b) the functions in question.

A remote controlled machinery *or related product* shall be designed and constructed in such a way that it will respond only to signals from the intended control units.

For autonomous mobile machinery or related product, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function.

3.3.1. Control devices

The driver shall be able to actuate all control devices required to operate the machinery from the driving position, except for functions, which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.

Where there are pedals, they shall be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They shall have a slip-resistant surface and be easy to clean.

Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with pre-set positions, shall return to the neutral position as soon as they are released by the operator.

In the case of wheeled machinery, the steering system shall be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.

Any control that locks the differential shall be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.

The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.

3.3.2. Starting/moving

All travel movements of self-propelled machinery with a ride-on driver shall be possible only if the driver is at the controls.

Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver shall be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

This also applies to all other parts which; to allow safe movement, have to be in particular positions, locked if necessary.

Where it does not give rise to other risks, movement of the machinery shall depend on safe positioning of the aforementioned parts.

It shall not be possible for unintentional movement of the machinery to occur while the engine is being started.

The movement of an autonomous mobile machinery ■ shall take into account the risks related to the area where it is intended to move and work.

3.3.3. Travelling function

Without prejudice to road traffic regulations, self-propelled machinery and its trailers shall meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.

The driver shall be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device shall be provided for slowing down and stopping.

Where safety so requires, a parking device shall be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, if it is purely mechanical.

Remote-controlled machinery shall be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

- (a) if the driver loses control;
- (b) if it receives a stop signal;
- (c) if a fault is detected in a safety-related part of the system;
- (d) if no validation signal is detected within a specified time.

Section 1.2.4 does not apply to the travelling function.

Autonomous mobile machinery *or related product* shall comply, ***with one or both where necessary according to the risk assessment***, of the following conditions:

- (a) it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;
- (b) it shall be equipped with devices intended to detect any human, domestic animal or any other obstacle in its vicinity, where those obstacles could give rise to a risk to health and safety of persons or of domestic animals or to safe operation of the machinery *or related* product.

The movements of mobile machinery *or related product* connected with one or more trailers or towed equipment, including autonomous mobile machinery *or related product*, connected with one or more trailers or towed equipment, shall not give rise to risks for persons, domestic animals or any other obstacle in the danger zone of such machinery *or related product* and trailers or towed equipment.

3.3.4. Movement of pedestrian-controlled machinery

Movement of pedestrian-controlled self-propelled machinery shall be possible only through sustained action on the relevant control device by the driver. In particular, it shall not be possible for movement to occur while the engine is being started. The control systems for pedestrian-controlled machinery shall be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:

- (a) crushing;
- (b) injury from rotating tools.

The speed of travel of the machinery shall be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it shall not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed shall be such that it does not endanger the driver.

3.3.5. Control circuit failure

A failure in the power supply to the power-assisted steering, where fitted, shall not prevent machinery from being steered during the time required to stop it.

For autonomous mobile machinery, a failure in the steering system shall not have an impact on the safety of the machinery.

3.4. PROTECTION AGAINST MECHANICAL RISKS

3.4.1. Uncontrolled movements

A machinery *or related* product shall be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2. Moving transmission parts

By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.

3.4.3. Roll-over and tip-over

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery shall be fitted with an appropriate protective structure, unless this increases the risk.

This structure shall be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer ■ shall, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.4. Falling objects

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery shall be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.

This structure shall be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer ■ shall, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.5. Means of access

Handholds and steps shall be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.

3.4.6. Towing devices

All machinery used to tow or to be towed shall be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.

Insofar as the tow bar load so requires, such machinery shall be equipped with a support with a bearing surface suited to the load and the ground.

3.4.7. Transmission of power between self-propelled machinery (or tractor) and recipient machinery

Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery shall be designed and constructed in such a way that any part that moves during operation is protected over its whole length.

On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached shall be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

It shall be possible to open this guard for access to the removable transmission device. Once it is in place, there shall be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.

On the recipient machinery side, the input shaft shall be enclosed in a protective casing fixed to the machinery.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device shall be marked accordingly.

All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), shall have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard shall be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard shall cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.

If means of access to working positions are provided near to the removable mechanical transmission device, they shall be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.

3.5. PROTECTION AGAINST OTHER RISKS

3.5.1. Batteries

The battery housing shall be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tip over and to avoid the accumulation of vapours in places occupied by operators.

A machinery *or related* product shall be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.

The batteries with automatic charging for mobile machinery, including autonomous mobile machinery *or related product*, shall be designed to prevent hazards referred to in sections 1.3.8.2. and 1.5.1., including the risks of contact or *collision* of the *machinery or related product* with a person or another *machinery or related product* when the *machinery or related product* moves autonomously to the charging station.

3.5.2. Fire

Depending on the hazards anticipated by the manufacturer, machinery shall, where its size permits:

- (a) either allow easily accessible fire extinguishers to be fitted; or
- (b) be provided with built-in extinguisher systems.

3.5.3. Emissions of hazardous substances

The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the **application of hazardous substances**. However, the operator shall be protected against the risk of exposure to such hazardous emissions.

Ride-on mobile machinery having **application of hazardous substances** as the main function shall be equipped with filtration cabs or equivalent safety measures.

3.5.4. Risk of contact with live overhead power lines

Depending on **its** height ■ , mobile machinery **or related** product shall, where relevant, be designed, constructed and equipped, so as to prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc between any part of the machinery or an operator driving the machinery and an energised overhead power line.

When the risk **to the persons operating machinery incurred by the contact** with an energised overhead power line cannot be fully avoided, mobile machinery **or related product** shall be designed, constructed and equipped **so as to prevent any** electrical **hazards**.

3.6. INFORMATION AND INDICATIONS

3.6.1. Signs, signals and warnings

All machinery **or related product** shall have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They shall be chosen, designed and constructed in such a way as to be clearly visible and indelible.

Without prejudice to the provisions of road traffic regulations, machinery *or related product* product with a ride-on driver shall have the following equipment:

- (a) an acoustic warning device to alert persons;
- (b) a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery *or related product* product intended solely for underground working and having no electrical power;
- (c) where necessary, there shall be an appropriate connection between a trailer and the machinery *or related product* product for the operation of signals.

Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing shall be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery *or related product* product, which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.

Machinery *or related product* shall be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices shall be provided with the means to check that they are in good working order and their failure shall be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery shall be provided to warn against approaching the machinery while it is working; the signs shall be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.

3.6.2. Marking

The following shall be shown legibly and indelibly on all machinery *or related* products:

- (a) nominal power expressed in kilowatts (kW);
- (b) mass of the most usual configuration, in kilograms (kg);

and, where appropriate:

- (a) maximum drawbar pull provided for at the coupling hook, in Newtons (N);
- (b) maximum vertical load provided for on the coupling hook, in Newtons (N).

3.6.3. Instructions *for use*

3.6.3.1. Vibrations

The instructions *for use* shall give the following information concerning vibrations, expressed as acceleration (m/s^2), transmitted by the machinery *or related products* to the hand-arm system or to the whole body:

- (a) the vibration total value from continuous vibrations to which the hand-arm system is subjected;
- (b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;
- (c) the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s^2 . Where this value does not exceed 0,5 m/s^2 , this shall be mentioned;

(d) the uncertainty of measurements.

These values shall be either those actually measured for the machinery *or related products* in question or those established on the basis of measurements taken for technically comparable machinery *or related products*, which is representative of the machinery *or related products* to be produced.

Where harmonised standards or *common* specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, the vibration shall be measured using the most appropriate measurement code for the machinery *or related products* concerned.

The operating conditions during measurement and the measurement codes used shall be described.

3.6.3.2. Multiple uses

The instructions for *use for* a machinery *or related* product allowing several uses depending on the equipment used and the instructions for *use for* the interchangeable equipment shall contain the information necessary for safe assembly and use of the basic machinery *or related* product and the interchangeable equipment that can be fitted.

3.6.3.3. Autonomous mobile machinery *or related* products

The instructions for use of autonomous mobile machinery *or related* products shall specify the characteristics of its intended travel, working areas and danger zones.

4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS

Machinery *or related product* presenting hazards due to lifting operations shall meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

4.1. GENERAL

4.1.1. Definitions

- (a) ‘Lifting operation’ means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level;
- (b) ‘Guided load’ means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points;
- (c) ‘Working coefficient’ means the arithmetic ratio between the load guaranteed by the manufacturer ■ up to which a component is able to hold it and the maximum working load marked on the component;
- (d) ‘Test coefficient’ means the arithmetic ratio between the load used to carry out the static or dynamic tests on *the* machinery or ■ lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory;
- (e) ‘Static test’ means the test during which ■ machinery or ■ lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred;

- (f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly;
- (g) 'Carrier' means a part of the machinery *or related product* on or in which persons and/or goods are supported in order to be lifted.

4.1.2. Protection against mechanical risks

4.1.2.1. Risks due to lack of stability

Machinery *or related products* shall be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the *instructions for use*. To that end, the manufacturer shall use the appropriate verification methods.

4.1.2.2. Machinery running on guide rails and rail tracks

Machinery shall be provided with devices, which act on the guide rails or tracks to prevent derailment.

If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices shall be provided which prevent the equipment, component or load from falling or the machinery from overturning.

4.1.2.3. Mechanical strength

Machinery *or* lifting accessories and their components shall be capable of withstanding the stresses to which they are subjected during their lifetime, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement shall also be satisfied during transport, assembly and dismantling.

Machinery *or* lifting accessories shall be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use ***and any reasonably foreseeable misuse***.

The materials used shall be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness, radiation and ageing.

Machinery *or* lifting accessories shall be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations shall take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:

- (a) manually-operated machinery *or* lifting accessories: 1,5;
- (b) other machinery ***or related products***: 1,25.

Machinery shall be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests shall be carried out under the least favourable conditions, as a general rule by combining the movements concerned.

4.1.2.4. Pulleys, drums, wheels, ropes and chains

Pulleys, drums and wheels shall have a diameter commensurate with the size of the ropes or chains with which they can be fitted.

Drums and wheels shall be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.

Ropes used directly for lifting or supporting the load shall not include any splicing other than at their ends. Splicings are, however, tolerated in installations, which are intended by design to be modified regularly according to needs of use.

Complete ropes and their endings shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.

Lifting chains shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.

In order to verify that an adequate working coefficient has been attained, the manufacturer shall, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.

4.1.2.5. Lifting accessories and their components

Lifting accessories and their components shall be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.

Moreover:

- (a) the working coefficient of wire-rope/rope-end combinations shall be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes shall not comprise any splices or loops other than at their ends;
- (b) where chains with welded links are used, they shall be of the short-link type. The working coefficient of chains shall be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;
- (c) the working coefficient for textile ropes, slings or webbing is dependent on the material, method of manufacture, dimensions and use. This coefficient shall be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes, slings or webbings shall not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;

- (d) all metallic components making up, or used with, a sling shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;
- (e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;
- (f) in order to verify that an adequate working coefficient has been attained, the manufacturer shall, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.

4.1.2.6. Control of movements

Devices for controlling movements shall act in such a way that the machinery *or related product* on which they are installed is kept safe.

- (a) Machinery *or related product* shall be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices shall, where appropriate, be preceded by a warning;
- (b) Where several fixed or rail-mounted *machinery or related* products can be manoeuvred simultaneously in the same place, with risks of collision, such machinery shall be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided;

- (c) Machinery *or related product* shall be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine;
- (d) It shall not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery *or related product* whose function requires it to operate in that way;
- (e) Holding devices shall be designed and constructed in such a way that inadvertent dropping of the loads is avoided.

4.1.2.7. Movements of loads during handling

The operating position of machinery shall be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery, which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads shall be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.

4.1.2.8. Machinery serving fixed landings

4.1.2.8.1. Movements of the carrier

The movement of the carrier of machinery serving fixed landings shall be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.

4.1.2.8.2. Access to the carrier

Where persons have access to the carrier, the machinery shall be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.

The machinery shall be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.

4.1.2.8.3. Risks due to contact with the moving carrier

Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone shall be rendered inaccessible during normal operation.

When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space shall be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.

4.1.2.8.4. Risk due to the load falling off the carrier

Where there is a risk due to the load falling off the carrier, the machinery shall be designed and constructed in such a way as to prevent this risk.

4.1.2.8.5. Landings

Risks due to contact of persons at landings with the moving carrier or other moving parts shall be prevented.

Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards shall be fitted in order to prevent this risk. Such guards shall not open in the direction of the travel zone. They shall be fitted with an interlocking device controlled by the position of the carrier that prevents:

- (a) hazardous movements of the carrier until the guards are closed and locked;
- (b) hazardous opening of a guard until the carrier has stopped at the corresponding landing.

4.1.3. Fitness for purpose

When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer **■** shall ensure, by taking appropriate measures or having them taken, that the machinery or **■** lifting accessories which are ready for use – whether manually or power-operated – can fulfil their specified functions safely.

The static and dynamic tests referred to in section 4.1.2.3 shall be performed on all lifting machinery ready to be put into service.

Where the machinery cannot be assembled in the manufacturer's premises **■**, the appropriate measures shall be taken at the place of use by the manufacturer **■**. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.

4.2. REQUIREMENTS FOR MACHINERY **OR RELATED** PRODUCTS WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT

4.2.1. Control of movements

Hold-to-run control devices shall be used to control the movements of the machinery or **related product or** its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery **or related product** colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.

4.2.2. Loading control

Machinery **or related product** with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm shall be fitted with devices to warn the driver and prevent dangerous movements in the event:

- (a) of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded; or
- (b) of the overturning moment being exceeded.

4.2.3. Installations guided by ropes

Rope carriers, tractors or tractor carriers shall be held by counterweights or by a device allowing permanent control of the tension.

4.3. INFORMATION AND MARKINGS

4.3.1. Chains, ropes and webbing

Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer ■ and the identifying reference of the relevant certificate.

The certificate mentioned above shall show at least the following information:

- (a) the name and address of the manufacturer ■ ;
- (b) a description of the chain or rope, which includes:
 - (i) its nominal size;
 - (ii) its construction;
 - (iii) the material from which it is made; and
 - (iv) any special metallurgical treatment applied to the material;
- (c) the test method used;
- (d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.

4.3.2. Lifting accessories

Lifting accessories shall show the following particulars:

- (i) identification of the material where this information is needed for safe use;
- (ii) the maximum working load.

In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph shall be displayed on a plate or other equivalent means and securely affixed to the accessory.

The particulars shall be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.

4.3.3. Lifting machinery

The maximum working load shall be prominently marked on the *lifting* machinery. This marking shall be legible, indelible and in an un-coded form.

Where the maximum working load depends on the configuration of the *lifting* machinery, each operating position shall be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.

Machinery intended for lifting goods only, equipped with a carrier, which allows access to persons, shall bear a clear and indelible warning prohibiting the lifting of persons. This warning shall be visible at each place where access is possible.

4.4. INSTRUCTIONS *FOR USE*

4.4.1. Lifting accessories

Each lifting accessory or each commercially indivisible batch of lifting accessories shall be accompanied by instructions setting out at least the following particulars:

- (a) the intended use;

- (b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e));
- (c) instructions for assembly, use and maintenance;
- (d) the static test coefficient used.

4.4.2. Lifting machinery

Lifting machinery shall be accompanied by instructions *for use* containing information on:

- (a) the technical characteristics of the *lifting* machinery, and in particular:
 - (i) the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3;
 - (ii) the reactions at the supports or anchors and, where appropriate, characteristics of the tracks;
 - (iii) where appropriate, the definition and the means of installation of the ballast;
- (b) the contents of the logbook, if the latter is not supplied with the *lifting* machinery;
- (c) advice for use, particularly to offset the lack of direct vision of the load by the operator;
- (d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer ■ ;
- (e) for *lifting* machinery, which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.

5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY *OR RELATED* PRODUCTS INTENDED FOR UNDERGROUND WORK

Machinery *or related product* intended for underground work shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

5.1. RISKS DUE TO LACK OF STABILITY

Powered roof supports shall be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They shall be equipped with anchorages for the top plates of the individual hydraulic props.

5.2. MOVEMENT

Powered roof supports shall allow for unhindered movement of persons.

5.3. CONTROL DEVICES

The accelerator and brake controls for movement of machinery running on rails shall be hand-operated. However, enabling devices may be foot-operated.

The control devices of powered roof supports shall be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices shall be protected against any accidental release.

5.4. STOPPING

Self-propelled machinery running on rails for use in underground work shall be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.

5.5. FIRE

Section 3.5.2 (b) is mandatory in respect of machinery *or related product*, which comprises highly flammable parts.

The braking system of machinery *or related product* intended for use in underground workings shall be designed and constructed in such a way that it does not produce sparks or cause fires.

Machinery *or related product* with internal combustion engines for use in underground workings shall be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.

5.6. EXHAUST EMISSIONS

Exhaust emissions from internal combustion engines shall not be discharged upwards.

6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY **OR RELATED** PRODUCTS PRESENTING PARTICULAR RISKS DUE TO THE LIFTING OF PERSONS

Machinery *or related product* presenting risks due to the lifting of persons shall meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

6.1. GENERAL

6.1.1. Mechanical strength

The carrier, including any trapdoors, shall be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery *or related product* intended for the lifting of persons and shall, as a general rule, be doubled. Machinery *or related product* intended for lifting persons or persons and goods shall be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.

6.1.2. Loading control for machinery *or related products* moved by power other than human strength

The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2. CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier shall, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

In operation, those control devices shall override any other devices controlling the same movement with the exception of emergency stop devices.

The control devices for the movements referred to in the first paragraph shall be of the hold-to-run type except where the carrier is completely enclosed. If there is no risk of persons or objects on the carrier colliding or falling and no other risks due to the upward and downward movements of the carrier, control devices authorising automatic stops at preselected positions may be used instead of hold-to-run type control devices

6.3. RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1. Risks due to movements of the carrier

Machinery *or related products* for lifting persons shall be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.

6.3.2. Risk of persons falling from the carrier

The carrier shall not tilt to an extent, which creates a risk of the occupants falling, including when the machinery *or related products* and carrier are moving.

Where the carrier is designed as a workstation, provision shall be made to ensure stability and to prevent hazardous movements.

If the measures referred to in section 1.5.15 are not adequate, carriers shall be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points shall be strong enough for the use of personal protective equipment against falls from a height.

Any trapdoor in floors or ceilings or side doors shall be designed and constructed in such a way as to prevent inadvertent opening and shall open in a direction that obviates any risk of falling, should they open unexpectedly.

6.3.3. Risk due to objects falling on the carrier

Where there is a risk of objects falling on the carrier and endangering persons, the carrier shall be equipped with a protective roof.

6.4. MACHINERY *OR RELATED PRODUCTS* SERVING FIXED LANDINGS

6.4.1. Risks to persons in or on the carrier

The carrier shall be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself shall be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors shall remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

■ Machinery *or related product* shall be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices shall be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.

The stopping action shall not cause deceleration harmful to the occupants, whatever the load conditions.

6.4.2. Controls at landings

Controls, other than those for emergency use, at landings shall not initiate movements of the carrier when:

- (a) the control devices in the carrier are being operated;
- (b) the carrier is not at a landing.

6.4.3. Access to the carrier

The guards at the landings and on the carrier shall be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

6.5. MARKINGS

The carrier shall bear the information necessary to ensure safety including:

- (a) the number of persons permitted on the carrier;
- (b) the maximum working load.

ANNEX IV

A. TECHNICAL DOCUMENTATION

TECHNICAL DOCUMENTATION FOR MACHINERY *AND RELATED* PRODUCTS

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the machinery *or related* product with the applicable essential health and safety requirements set out in Annex III.

The technical documentation shall include at least the following elements:

(a) a complete description of the machinery *or related* product and of its intended use;

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(ba) *the documentation on risk assessment demonstrating the procedure carried out, including:*

(i) *a list of the essential health and safety requirements that are applicable to the machinery or related product;*

(ii) *the description of the protective measures implemented to meet each applicable essential health and safety requirement and, when appropriate, the indication of the residual risks associated with the machinery or related product;*

█
(d) design and manufacturing drawings and schemes of the machinery *or related* product and of its components, sub-assemblies and circuits;

- (e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the machinery *or related* product;
 - (f) the references of the harmonised standards *referred to in Article 17(1) or common specifications* adopted by the Commission in accordance with Article 17(3) that have been applied for the design and manufacture of the machinery *or related product*. In the event of partial application of harmonised standards *or common specifications*, the documentation shall specify the parts, which have been applied;
 - (g) where harmonised standards *or common specifications* have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to *meet each* applicable essential health and safety requirements;
 - (h) *reports and/or* results of the design calculations, *tests*, inspections and examinations carried out to verify the conformity of the machinery *or related product* with the applicable essential health and safety requirements;
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- (j) a description of the means used by the manufacturer during the production of the machinery *or related product* to ensure the conformity of the machinery *or related product* produced with the design specifications;
 - (k) a copy of the manufacturer's instructions *for use* and the information set out in section 1.7.4 of Annex III;

- (l) where appropriate, the declaration of incorporation for partly completed machinery set out in Annex V and the relevant assembly instructions for such machinery;
- (la) ***where appropriate, copies of the EU declaration of conformity of machinery or related products as well as any product covered by other EU harmonisation legislations incorporated into the machinery or related product;***
- (m) for machinery ***or related*** products produced in series, the internal measures that will be implemented to ensure that the machinery ***or related*** product remains in conformity with this Regulation;
- (n) the source code or ***programming*** logic of the safety related software to demonstrate the conformity of the machinery ***or related*** product with this Regulation further to a reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III;
- (o) for sensor-fed, remotely-driven, or autonomous machinery ***or related*** product, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used **■** ;
- (p) the results of research and tests on components, fittings or the **■** machinery ***or related product*** carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and put into service safely.

B. RELEVANT TECHNICAL DOCUMENTATION FOR PARTLY COMPLETED MACHINERY

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the partly completed machinery with the applicable essential health and safety requirements set out in Annex III.

The technical documentation shall include at least the following elements:

- (a) a complete description of the partly completed machinery and of its intended *function when incorporated into or assembled with machinery or other partly completed machinery or equipment*;
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 - (ba) *the risk assessment documentation showing the procedure carried out, including:*
 - (i) *a list of the essential health and safety requirements which apply to the partly completed machinery;*
 - (ii) *the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks;*
- (c) design and manufacturing drawings and schemes of the partly completed machinery and of its components, sub-assemblies and circuits;
- (d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (c) and of the operation of the partly completed machinery;

- (e) the references of the harmonised standards referred to in Article 17(1) *or common specifications adopted by the Commission in accordance with Article 17(3)* that have been applied for the design and manufacture of the partly completed machinery. In the event of partial application of harmonised standards *or common specifications*, the documentation shall specify the parts, which have been applied;
 - (f) where harmonised standards *or common specifications* have not been applied or have been only partially applied, description of the other technical specifications that have been applied in order to *meet each* applicable essential health and safety requirements;
 - (g) *reports and/or* results of the design calculations, *tests*, inspections and examinations carried out to verify the conformity of the partly completed machinery with the applicable essential health and safety requirements;
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- (i) a description of the means used by the manufacturer during the production of the partly completed machinery to ensure the conformity of the partly completed machinery produced with the design specifications;
 - (j) a copy of the assembly instructions for the partly completed machinery set out in ■ Annex X;
 - (k) for partly completed machinery ■ produced in series, the internal measures that will be implemented to ensure that the partly completed machinery ■ remains in conformity with the essential health and safety requirements applied;

- (l) the source code or **programming** logic of the safety related software upon a reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III:
 - (m) for sensor-fed, remotely-driven, or autonomous partly completed machinery, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used **■** ;
 - (n) the results of research and tests on components, fittings or the **partly** completed machinery carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and **incorporated** safely.
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ANNEX V

EU DECLARATION OF CONFORMITY AND INCORPORATION

A. EU DECLARATION OF CONFORMITY OF MACHINERY *AND RELATED PRODUCT* No...²⁰



The EU declaration of conformity shall contain the following particulars:

1. The *machinery or related product* (product, type, *model*, batch or serial number):
 - 1a. *Where applicable: substantially modified machinery:*
 2. Name and address of the manufacturer and, where applicable, his or her authorised representative:
 3. *For lifting machinery which is intended to be permanently installed in a building or a structure and which cannot be assembled in the manufacturer's premises but can only be assembled at the place of use, the address of that place:*
 4. This declaration of conformity is issued under the sole responsibility of the manufacturer:
 5. Object of the declaration (identification of machinery *or related* product allowing traceability; where necessary for the identification of the machinery *or related* product, a colour image of sufficient clarity may be included):
 6. The object of the declaration described in point 5 is in conformity with the relevant Union harmonisation legislation:

²⁰ It is optional for the manufacturer to assign a number to the declaration of conformity.

7. References to the **■** harmonised standards *referred to in Article 17(1) or common specifications* adopted by the Commission in accordance with Article 17(3) *that have been applied*, including the date of the standard *or of the common specification*, or references to the other technical specifications, including *their date*, in relation to which conformity is declared. *In the event of partial application of harmonised standards or common specifications, the EU declaration of conformity shall specify the parts, which have been applied*:
8. Where applicable, the notified body ... (name, number) ... performed the EU type-examination (Module B) and issued the EU type-examination certificate ... (reference to that certificate), followed by conformity to type based on internal production control (module C) *or the conformity based on unit verification (module G) or full quality assurance (module H)*:
9. Where applicable, the machinery *or related* product is subject to the conformity assessment procedure *based on* internal production control (Module A) **■** :
10. Additional information:
Signed for and on behalf of: ...
(place and date of issue):
(name, function) (signature):

B. EU DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY No...²¹

The declaration of incorporation shall contain the following particulars:

1. Partly Completed Machinery (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his or her authorised representative:
3. This declaration of incorporation is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of partly completed machinery allowing traceability; where necessary for the identification of the partly completed machinery, a colour image of sufficient clarity may be included):
5. A sentence declaring which essential requirements of Regulation (EU) .../..... of the European Parliament and of the Council²² are applied and fulfilled and that the relevant technical documentation was drawn-up in accordance with part B of Annex IV, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Union harmonisation legislation:

²¹ It is optional to assign a number to the declaration of conformity.

²² OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote.

6. References to the **■** harmonised standards *referred to in Article 17(1) or common specifications* adopted by the Commission in accordance with Article 17(3) *that have been applied*, including the date of the standard *or of the common specification*, or references to the other technical specifications, including *their date*, in relation to which conformity is declared. *In the event of partial application of harmonised standards or common specifications, the declaration of incorporation shall specify the parts, which have been applied*:
7. An undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery:
8. A statement that the partly completed machinery shall not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with this Regulation **■** :
9. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

ANNEX VI

INTERNAL PRODUCTION CONTROL

(Module A)

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his or her sole responsibility that the machinery *or related* product *concerned* satisfies the applicable requirements of this Regulation.

2. Technical documentation

The manufacturer shall draw up the technical documentation described in Annex IV, *Part A*.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured machinery *or related* product with the technical documentation referred to in point 2 and with the applicable requirements of this Regulation.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual machinery *or related* product that satisfies the applicable requirements of this Regulation.

- 4.2. The manufacturer shall draw up an EU declaration of conformity for each machinery *or related* product model in accordance with Article **18** and keep it, together with the technical documentation, at the disposal of the national authorities for ten years after the machinery *or related* product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery *or related* product for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

ANNEX VII

EU TYPE-EXAMINATION

(Module B)

1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a machinery *or related* product and verifies and attests that the technical design of the machinery *or related* product meets the applicable requirements of this Regulation.
2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the machinery *or related* product through examination of the technical documentation, plus examination of a specimen of the machinery *or related* product that is representative of the production envisaged (production type).
3. Application for EU type-examination

The manufacturer shall lodge an application for EU type-examination with a single notified body of his or her choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;
- (b) a written declaration that the same application has not been lodged with any other notified body;

- (c) the technical documentation described in Annex IV;
- (d) **the access to** the specimen(s) of the machinery **or related** product representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme. For machinery or related products produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, while for machinery or related products produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.

4. EU type-examination

The notified body shall:

- (a) examine the technical documentation to assess the adequacy of the technical design of the machinery **or related** product. In conducting such an examination, Annex IV, second subparagraph, point (j), need not be taken into account;
- (b) for machinery **or related** products produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;
- (c) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or **common** specifications adopted by the Commission in accordance with Article 17(3), as well as the elements that have been designed in accordance with other technical specifications;

- (d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, *or common specifications adopted by the Commission in accordance with Article 17(3)*, those have been applied correctly;
- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or *common* specifications adopted by the Commission in accordance with Article 17(3) have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.

5. Evaluation report

The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, ■ the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. EU type-examination certificate

- 6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.

The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.

- 6.2. The EU type-examination certificate shall contain at least the following information:
 - (a) the name and identification number of the notified body;

- (b) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;
- (c) an identification of the machinery *or related* product covered by the certificate (type number);
- (d) a statement that the machinery *or related* product type complies with the applicable essential health and safety requirements;
- (e) where harmonised standards or *common* specifications adopted by the Commission in accordance with Article 17(3) have been fully or partially applied, the references of those standards *or common specifications* or parts thereof;
- (f) where other technical specifications have been applied, the references of those technical specifications;

■

- (h) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;
- (i) any conditions attached to the issuing of the certificate.

6.3. The EU type-examination certificate may have one or more annexes attached.

6.4. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. Review of the EU type-examination certificate
 - 7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art, which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
 - 7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type- examination certificate of all modifications to the approved type and of all modifications to the technical documentation that may affect the conformity of the machinery *or related* product with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.
 - 7.3. The manufacturer shall ensure that the machinery *or related* product continues to fulfil the applicable essential health and safety requirements in light of the state of the art.
 - 7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate either:
 - (a) in the case of a modification to the approved type referred to in point 7.2;

- (b) in the case of a change in the state of the art referred to in point 7.3;
- (c) at the latest, before the date of expiry of the certificate. ***In this case, the review may lead to a renewal of the EU type certificate only when the application is submitted by the manufacturer at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate. Otherwise, the review may lead only to an approval in the form of an addition to the original EU type-examination certificate and the expiry date of the certificate shall be the one of the original certificate.***



- 7.5. The notified body shall examine the machinery ***or related*** product type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable essential health and safety requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.
- 7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following:
- (a) his or her name and address and data identifying the EU type-examination certificate concerned;

- (b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or *common* specifications adopted by the Commission in accordance with Article 17(3) or other technical specifications applied;
- (c) confirmation that there has been no change in the state of the art as referred to in point 7.3; and
- (d) where not already supplied, copies of current product drawings and photographs, product marking and information;

Where the notified body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In that case, the notified body shall renew the EU type-examination certificate.

The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.

If the notified body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.

- 7.7. If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the machinery *or related* product concerned.
8. Each notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto, which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the EU type-examination certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for 10 years after the machinery *or related* product has been placed on the market *or put into service*.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.

ANNEX VIII

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

(Module C)

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his or her sole responsibility that the machinery **or related** product concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery **or related** product with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.

3. CE marking and EU declaration of conformity

3.1. The manufacturer shall affix the CE marking to each individual machinery **or related** product that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

3.2. The manufacturer shall draw up **an** EU declaration of conformity for a machinery **or related** product model and keep it at the disposal of the national authorities for 10 years after the machinery **or related** product has been placed on the market **or put into service**. The EU declaration of conformity shall identify the machinery **or related** product for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

ANNEX IX

CONFORMITY BASED ON FULL QUALITY ASSURANCE

(Module H)

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his or her sole responsibility that the machinery *or related* product concerned *satisfies* the requirements of this Regulation that apply to *it*.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the machinery *or related* product concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his or her quality system with the notified body of his or her choice, for the machinery *or related* product concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;
- (b) the technical documentation for one model of each category of *machinery or related* products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least **■** :

█
(via) *the elements set out in points a), b), d), e), f), g) and h) of Annex IV part A; and*

(vii) the documentation concerning the quality system; and

(viii) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the *machinery or related* products with the requirements of this Regulation that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or *other technical specifications or common specifications* adopted by the Commission in accordance with Article 17(3) █ will not be applied in full, the means that will be used to ensure that the essential *health and safety* requirements of this Regulation that apply to the *machinery or related* product will be met;

- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the machinery *or related* product ■ ;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (e) the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out;
- (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the ■ relevant harmonised standard ■ .

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant *machinery or related* product field and the technology concerned, and with knowledge of the applicable *essential health and safety* requirements *set out in Annex III* of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b), point (ii), to verify the manufacturer's ability to identify the applicable *essential health and safety* requirements *set out in Annex III* of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the *machinery or related* product with those requirements.

The manufacturer or his or her authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body
 - 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
 - 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
 - (a) the quality system documentation;
 - (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
 - (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
 - 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
 - 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. **CE** marking and **EU** declaration of conformity

- 5.1. The manufacturer shall affix the required **CE** marking set out in this Regulation, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of this Regulation.
- 5.2. The manufacturer shall draw up a written **EU** declaration of conformity for each machinery **or related** product model and keep it at the disposal of the national authorities for ten years after the machinery **or related** product has been placed on the market **or put into service**. **The EU** declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the **EU** declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least ten years after the machinery **or related** product has been placed on the market **or put into service**, keep at the disposal of the national authorities:
- (a) the technical documentation referred to in point 3.1;
 - (b) the documentation concerning the quality system referred to in point 3.1**(b)(ii)**;
 - (c) **the information relating to** the change referred to in point 3.5, as approved;
 - (d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying **authority** of quality system **approval decisions** issued or withdrawn, and shall, periodically or upon request, make available to its notifying **authority** the list of quality system **approval decisions** refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system **approval decisions**, which it has refused, suspended or withdrawn, and, upon request, of quality system **approval decisions**, which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

ANNEX IXa

CONFORMITY BASED ON UNIT VERIFICATION

(Module G)

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his or her sole responsibility that the machinery or related product, which has been subject to the provisions of point 4, is in conformity with the essential health and safety requirements set out in Annex III.

2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the machinery or related product's conformity with the relevant essential health and safety requirements set out in Annex III, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable essential health and safety requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the machinery or related product.

The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;**
- (b) the technical documentation for the unit of machinery or related products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least:**

- (i) the elements set out in points a), b), d), e), f), g) and h) of Annex IV part A; and*
- (ii) the documentation concerning the quality system; and*
- (iii) a written declaration that the same application has not been lodged with any other notified body.*

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the machinery or related product has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery or related product with the applicable essential health and safety requirements set out in Annex III.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications, or equivalent tests, to check the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III, or have them carried out. In the absence of such a harmonised standard and/or common specification the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate in respect of the examinations and tests carried out and shall affix its identification number to the approved machinery or related product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates at the disposal of the national authorities for 10 years after the machinery or related product has been placed on the market.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the required CE marking set out in Article 10.2 and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each machinery or related product that satisfies the applicable essential health and safety requirements set out in Annex III.

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the machinery and related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery and related product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his or her behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX X

ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY

1. The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in ***machinery or other partly completed machinery or equipment***, and that the ***machinery or other partly completed machinery or equipment with the incorporated partly completed machinery*** does not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.

2. The assembly instructions shall ***contain relevant information to be used in the instructions*** of the ***machinery or other partly completed machinery or equipment***, in which the partly completed machinery is to be assembled. ***Each assembly instruction shall contain, where applicable, at least the following information:***

- (a) ***a general description of the partly completed machinery;***
- (b) ***the drawings, diagrams, descriptions and explanations necessary for the incorporation into the final machinery, maintenance and repair of the partly completed machinery and for checking its correct functioning;***
- (c) ***warnings concerning ways in which the partly completed machinery shall not be used that experience has shown might occur;***
- (d) ***assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the partly completed machinery is to be mounted;***

- (e)** *information regarding noise or vibration which is likely to be reduced by the incorporation;*
- (f)** *information about the essential health and safety requirements set out in Annex III which are applicable to the partly completed machinery;*
- (g)** *the essential characteristics of tools, which may be fitted to the partly completed machinery;*
- (h)** *the conditions in which the partly completed machinery meets the requirement of stability, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;*
- (i)** *instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the partly completed machinery and of its various parts where these are regularly to be transported separately;*
- (j)** *the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;*
- (k)** *the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the design;*

(l) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;

(m) the specifications of the spare parts to be used, when these affect the health and safety of operators;

(n) a clear description of which version of the assembly instructions corresponds to the partly completed machinery model.

If the partly completed machinery is intended to be used in machinery covered by annex III point 2 to 6, the assembly instructions must also contain relevant information to be used in the instructions for use for these machinery.

3. The assembly instructions for partly completed machinery shall contain the EU declaration of incorporation, or the internet address or machine readable code where the EU declaration of incorporation can be accessed.

ANNEX XI

CORRELATION TABLE

Directive 2006/42/EC	This Regulation
Article 1	Article 2
Article 2	Article 3
Article 3	Article 8 and Article 9
Article 4	-
Article 5	Article 7
Article 6	Article 4
Article 7	Article 17 (1)
Article 8 (1)	Article 45
Article 8 (2)	-
Article 9	-
Article 10	Article 42 (3)
Article 11	Article 41 to Article 44
Article 12	Article 21
Article 13	Article 22
Article 14	Article 24 to Article 40
Article 15	Article 23
Article 16	Article 19
Article 17	Article 20

Article 18	Article 47
Article 19	-
Directive 2006/42/EC	This Regulation
Article 20	-
Article 21	Article 51
Article 21 a	Article 45
Article 22	Article 46
Article 23	Article 48
Article 24	-
Article 25	Article 49
Article 26	-
Article 27	-
Article 28	Article 52
Article 29	Article 52
Annex I - General principles	Annex III - General principles
Annex I, Section 1	Annex III, Section 1
Annex I, Section 2	Annex III, Section 2
Annex I, Section 3	Annex III, Section 3
Annex I, Section 4	Annex III, Section 4
Annex I, Section 5	Annex III, Section 5
Annex I, Section 6	Annex III, Section 6
Annex II, Parts A and B	Annex V

Annex III	-
Annex IV	Annex I
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Annex VII, Parts A and B	Annex IV, Parts A and B
Directive 2006/42/EC	This Regulation
Annex VIII	Annex VI
Annex IX	Annex VII
Annex X	Annex VIII
Annex XI	Article 28