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

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I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2023/1230 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 14 June 2023

on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

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

Whereas:

(1) Directive 2006/42/EC of the European Parliament and of the Council ([3]) 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.

(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, for protecting the environment, notably in relation to the risks arising out of the intended use or any reasonably foreseeable misuse of machinery or related products. For the avoidance of doubt, domestic animals should be considered to include farm animals.

([1]) OJ C 517, 22.12.2021, p. 67.
([2]) Position of the European Parliament of 18 April 2023 (not yet published in the Official Journal) and decision of the Council of 22 May 2023.
([3]) 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).

(6) Regulation (EC) No 765/2008 of the European Parliament and of the Council ([4]) lays down rules on the accreditation of conformity assessment bodies, and 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 for a high level of protection of public interests such as the protection of the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, of the environment.

(7) Regulation (EU) 2019/1020 of the European Parliament and of the Council ([5]) 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 insofar as there are no specific provisions with the same objective, which regulate in a more specific manner particular aspects of market surveillance and enforcement.

(8) 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 Regulation (EU) 2019/1020 in respect of those products.

(9) Decision No 768/2008/EC of the European Parliament and of the Council ([6]) 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, insofar 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.

(10) This Regulation should cover products which are new to the Union market when placed on the market, and are either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.

(11) Where there is a possibility that 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 of and experience in handling machinery or related products in the design and construction of the products. The same applies where the machinery or related product is normally used to provide a service to a consumer.

(12) 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 (for example construction sites). The Commission Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and Robotics of 19 February 2020, 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.

([4]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

([5]) 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.)

([6]) 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).

(13) In order to ensure protection of the health and safety of persons, and, where appropriate, domestic animals and property, and, where applicable, of 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 Regulation (EU) 2019/1020.

(14) 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.

(15) 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.

(16) In order to avoid legislating twice on the same product, it is appropriate to exclude from the scope of this Regulation weapons, including firearms, that are subject to Directive (EU) 2021/555 of the European Parliament and of the Council ([7]).

(17) 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 although it should still apply to the 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 except in respect of risks that might arise from circulation on public roads. 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 167/2013 of the European Parliament and of the Council ([8]) or Regulation (EU) No 168/2013 of the European Parliament and of the Council ([9]) or approval under Regulation (EU) 2018/858 of the European Parliament and of the Council ([10]) are covered by this Regulation.

(18) 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 electric motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council ([11]) and should therefore be excluded from the scope of this Regulation. Some of those products, for example washing machines, are progressively incorporating Wi-Fi functions and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council ([12]) as radio equipment. Those products should also be excluded from the scope of this Regulation.

(19) 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 machinery design. Consequently, the definition of machinery should be adapted. In this respect, machinery missing only the upload of 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 which is placed independently on the market should be considered a safety component.

([7]) Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).

([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).

([10]) Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

([11]) 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 (OJ L 96, 29.3.2014, p. 357).

([12]) 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).

(20) 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 procedures and included in Annex I.

(21) Partly completed machinery is a product within the scope of this Regulation which needs to undergo further construction in order to be able to perform its specific application, namely 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.

(22) 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 which are also wholly or partly covered by more specific Union harmonisation legislation than this Regulation, 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 might 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 might 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 Wi-Fi function.

(23) For trade fairs, exhibitions and demonstrations or similar events, it should be possible to display 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.

(24) The evolution of the state of the art in the machinery sector has an impact on the classification of categories of machinery or related products listed in Annex I. With a view to properly reflecting any categories of machinery or related products presenting a higher risk factor, criteria should be established for the assessment of categories of products which should be included in the list of categories of machinery or related products subject to a stricter conformity assessment procedure.

(25) 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 legal acts specifically addressing cybersecurity aspects.

(26) 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, to 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 or 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 machinery or related products that are part of an assembly of machinery, and that are not affected by the modification.

(27) In the machinery sector, approximately 98 % of 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 assessment and reducing them proportionately to the specific interests and needs of SMEs.

(28) 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 the protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, domestic animals, property, and, where applicable, of the environment, as well as fair competition on the Union market.

(29) 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.

(30) In order to facilitate communication between economic operators, market surveillance authorities and users, manufacturers and importers should indicate a website, email address or other digital contact in addition to the postal address.

(31) 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.

(32) 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 essential health and safety requirements are applicable to the product within the scope of this Regulation and which measures need to be taken to address the risks that the product might present. The risk assessment should also address future updates or developments of 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 might arise during the product's lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy.

(33) 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 products 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.

(34) It is essential that, before drawing up the EU declaration of conformity or the EU declaration of incorporation, the manufacturer prepare technical documentation. The manufacturer should be required to make that technical documentation available to national authorities on request or to notified bodies in the context 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.

(35) A person who manufactures machinery or related products for his or her own use is considered as to be a manufacturer and should be required to 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 is used by the manufacturer itself. However, such machinery needs to comply with this Regulation before it is put into service.

(36) 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, and, where appropriate, to domestic animals and property, and, where applicable, to 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, and, where appropriate, domestic animals and property, and, where applicable, to 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 the case of machinery and related products, is affixed and technical documentation drawn up by manufacturers is available for inspection by the competent national authorities.

(37) When placing products within the scope of this Regulation on the market, importers should indicate on those products their respective names, registered trade names or registered trade marks, postal addresses, websites, email addresses or other digital contacts at which they 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 importers would have to open the packaging to put their names and addresses on the product.

(38) 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 its handling of the product within the scope of this Regulation does not adversely affect its compliance with the requirements set out in this Regulation.

(39) With a view to 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, while 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.

(40) Instructions and other relevant documentation may be provided in a digital printable format. However, the manufacturer should ensure that distributors can provide, at the request of the user 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 user can request the instructions to be dispatched by mail.

(41) 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.

(42) Any economic operator who either places a product within the scope of this Regulation on the market under its 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 might be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(43) 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.

(44) 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 in respect of which the 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 Council ([13]) for the purpose of expressing the detailed technical specifications of those requirements.

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

(45) The current EU standardisation framework which is based on the New Approach principles set out in Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards ([14]) and on Regulation (EU) No 1025/2012 represents the framework by default to elaborate standards that provide for a 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 adopt implementing acts establishing common specifications for the essential health and safety requirements of this Regulation, provided that in doing so it duly respects the role and functions of standardisation organisations, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with those 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.

(46) 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.

(47) 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 during which the publication in the *Official Journal of the European Union* of the reference to the standard, its corrigendum or its amendment is expected and which should not exceed one year after the deadline for drafting a European standard set in accordance with Regulation (EU) No 1025/2012.

(48) 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 the products within the scope of this Regulation with the relevant essential health and safety requirements is demonstrated in the technical file.

(49) 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.

(50) 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.

(51) With a view to 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 in respect of which conformity to the appropriate extent can be presumed as the result of a certificate or statement of conformity issued under a relevant cybersecurity certification scheme adopted in accordance with Regulation (EU) 2019/881 of the European Parliament and of the Council ([15]).

(52) 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 by other Union legal acts to draw up an EU declaration of conformity. 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 legal 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.

([14]) OJ C 136, 4.6.1985, p. 1.

([15]) 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).

(53) The harmonised standards relevant to this Regulation should take into account the requirements of Directive (EU) 2019/882 of the European Parliament and of the Council ([16]) and the United Nations Convention on the Rights of Persons with Disabilities ([17]).

(54) The list of products in Annex IV of Directive 2006/42/EC has until now been 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 might present higher risk factors, regardless of such intended use or any reasonably foreseeable misuse. For example, systems with self-evolving behaviour 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 component or a system with self-evolving behaviour 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, where machinery embeds a system of which the safety component has already been subject to third party conformity assessment when it was placed independently on the market, that machinery should not have to be re-certified by a third party solely on the basis of the embedding of that system.

(55) 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.

(56) 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.

(57) 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.

(58) 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.

(59) 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.

(60) 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.

(61) 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.

([16]) Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70).
([17]) OJ L 23, 27.1.2010, p. 35.

(62) 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.

(63) 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.

(64) 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.

(65) 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 or related products 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.

(66) 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.

(67) 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.

(68) Market surveillance is an essential instrument to ensure the proper and uniform application of Union law. It is therefore appropriate to put in place a legal framework within which market surveillance can be carried out in an appropriate manner with regard to products within the scope of this Regulation.

(69) Member States should take all appropriate measures to ensure that machinery and related products may be placed on the market or put into service only if, where properly installed and maintained and used for its intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health or safety of persons, in particular consumers and professional users, and, where appropriate, of 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 and related products 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.

(70) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard or of common specifications 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.

(71) 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.

(72) 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 presenting a risk to the health or safety of persons and, where appropriate, domestic animals and property, and, where applicable, to 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.

(73) 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 in a harmonised standard or in common specifications.

(74) 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 categories of machinery and related products in Annex I and the indicative list of safety components in Annex II, and if necessary of supplementing the obligations of Member States to provide data and 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 category of machinery or related products 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 carry out appropriate consultations during its preparatory work, including with the stakeholders concerned and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([18]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(75) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission for the establishment of a uniform template for the collection of data and information for the purpose of adding a category of machinery or related products to Annex I or withdrawing a category of machinery or related products from Annex I, for the establishment of common specifications for the essential health and safety requirements set out in Annex III, for 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 for establishing whether a national measure in respect of compliant products within the scope of this Regulation which are found by a Member State to present a risk to the health and safety of persons, in particular consumers and professional users, or, where appropriate, to domestic animals or property, or, where applicable, to the environment, is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([19]).

(76) 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 issue guidance regarding the collection and transmission of comparable, high-quality data and information.

(77) 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 present 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.

(78) 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.

([18]) OJ L 123, 12.5.2016, p. 1.

([19]) 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).

(79) 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.

(80) 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.

(81) The traceability of machinery data required for the technical file and for market surveillance purposes should comply with confidentiality rules to protect manufacturers.

(82) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are implemented. The penalties provided for should be effective, proportionate and dissuasive.

(83) Since the objective of this Regulation, namely to ensure that the products within the scope of this Regulation placed on the market fulfil the requirements providing for a high level of protection of the health and safety of persons, and, where appropriate, domestic animals and property, and, where applicable, of 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.

(84) By including machinery and lifting accessories and chains and ropes in its scope, Directive 2006/42/EC has completely superseded Council Directive 73/361/EEC ([20]). Directive 73/361/EEC should therefore be repealed.

(85) 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.

(86) 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:

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 them to be made available on the market or put 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, of domestic animals and property, and, where applicable, of the environment. It also establishes rules on the free movement of products within the scope of this Regulation in the Union.

Article 2

Scope

1. This Regulation applies to machinery and the following related products:

(a) interchangeable equipment;

([20]) 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).

(b) safety components;

(c) lifting accessories;

(d) chains, ropes and webbing;

(e) removable mechanical transmission devices.

This Regulation also applies to partly completed machinery.

For the purposes of this Regulation, machinery, the related products listed in the first subparagraph and partly completed machinery shall together be referred to as 'products within the scope of this Regulation'.

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 of that installation;

(d) weapons, including firearms;

(e) means of transport by air, on water and on rail networks except for machinery mounted on those means of transport;

(f) aeronautical products, parts and equipment that fall within the scope of Regulation (EU) 2018/1139 of the European Parliament and of the Council ([21]) and the definition of machinery under this Regulation, insofar as Regulation (EU) 2018/1139 covers the relevant essential health and safety requirements set out in this Regulation;

(g) motor vehicles and their trailers, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, which fall within the scope of Regulation (EU) 2018/858, except for machinery mounted on those vehicles;

(h) 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 Regulation (EU) No 168/2013, except for machinery mounted on those vehicles;

(i) 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 Regulation (EU) No 167/2013, except for machinery mounted on those tractors;

(j) motor vehicles exclusively intended for competition;

(k) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;

(l) machinery or related products specially designed and constructed for military or police purposes;

(m) machinery or related products specially designed and constructed for research purposes for temporary use in laboratories;

(n) mine winding gear;

(o) machinery or related products intended to move performers during artistic performances;

([21]) 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).

(p) the following electrical and electronic products, insofar as they fall within the scope of Directive 2014/35/EU or of 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;

(q) the following high-voltage electrical products:

(i) switchgear and control gear;

(ii) transformers.

Article 3

Definitions

For the purposes of this Regulation, the following definitions 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) and (c), or of partly completed machinery, 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) to (e) missing only the uploading of the software intended for the specific application foreseen by the manufacturer;

(2) 'interchangeable equipment' means a device which, after the putting into service of 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 to attribute a new function to it, provided that the device is not a tool;

(3) 'safety component' means a physical or digital component, including software, of a product 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 endanger the safety of persons, but which is not necessary in order for that product to function or for which normal components may be substituted in order for that product to function;

(4) '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, which, if it fails, could result in an increase of that risk;

(5) 'lifting accessory' means a component or equipment, not attached to the lifting machinery, which enables 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;

(6) 'chains' means chains designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

(7) 'ropes' means ropes designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

(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 other machinery or related products by joining them at the first fixed bearing; when it is placed on the market with a guard, the device and the guard are to be regarded as one item;

(10) 'partly completed machinery' means an assembly which is not yet machinery as it cannot in itself 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 machinery;

(11) 'making available on the market' means any supply of a product within the scope of this Regulation 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;

(14) 'essential health and safety requirements' means the mandatory provisions, set out in Annex III, relating to the design and construction of products within the scope of this Regulation to ensure a high level of protection of the health and safety of persons, and, where appropriate, domestic animals and property, and, where applicable, of the environment;

(15) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(16) 'substantial modification' means a modification of machinery or a 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:

(a) the addition of guards or protective devices to that machinery or related product the processing of which necessitates the modification of the existing safety control system; or

(b) the adoption of additional protective measures to ensure the stability or mechanical strength of that machinery or related product;

(17) '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 to ensure that it remains fit for purpose during its entire lifetime;

(18) 'manufacturer' means any natural or legal person who:

(a) manufactures products within the scope of this Regulation or who has those products designed or manufactured, and markets those products under its name or trademark; or

(b) manufactures products within the scope of this Regulation, and puts those products into service for its own use;

(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 its 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 or the distributor;

(23) 'technical specifications' 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, point 1, point (c), of Regulation (EU) No 1025/2012;

(25) 'CE marking' means a marking by which the manufacturer indicates that machinery or a 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 for demonstrating whether the applicable essential health and safety requirements in 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 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 a user;

(33) 'withdrawal' means, for a product, any measure aimed at preventing a product within the scope of this Regulation that is in the supply chain from being made available on the market;

(34) 'lifetime' means the period from the moment that machinery or a 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;

(35) '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 and understandable to humans;

(36) 'professional user' means a natural person who uses or operates machinery or a 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 made 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 5

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 the modification of machinery or a related product in a way that is not compatible with this Regulation.

Article 6

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

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 referred to in Article 25(2), and machinery and related products that fall within the categories listed in Annex I, Part B shall be subject to the specific conformity assessment procedures referred to in Article 25(3).

2. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex I, after consulting the stakeholders concerned, in the light of technical progress, advances in 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 products, withdrawing an existing category of machinery or related products from that list or moving a category of machinery or related products from one Part of Annex I to another Part of that Annex, in accordance with the criteria and the procedures laid down in paragraphs 4, 5 and 7 of this Article.

3. Before adopting a delegated act, the Commission shall seek the views of experts in the relevant expert group in accordance with Article 47(4).

4. The Commission shall assess the seriousness of the inherent potential risk presented by a category of machinery or related product for the purpose of determining whether to add that category of machinery or related product to Annex I or to withdraw that 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, where relevant, be taken into account:

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

(b) the severity of harm which a person would suffer, including the degree of reversibility of that harm;

(c) the number of persons potentially affected by the harm;

(d) the frequency and the duration of the exposure to the hazard that a person would be exposed to in the course of the intended use or any reasonably foreseeable misuse of the category of machinery or related product;

(e) the possibilities of avoiding or limiting harm;

(f) in the case of safety components, the likelihood of serious consequences for the safety of the persons exposed to harm in the event of their failure.

5. When conducting the assessment referred in paragraph 4, 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 their intended use or following any reasonably foreseeable misuse;

(b) information about safety defects detected in the course of market surveillance, and material possibly available in the information systems administered by the Commission;

(c) information about known accidents and serious 'close calls', including the characteristics of those accidents or 'close calls';

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

In addition to points (a) to (d) of this paragraph, the Commission shall take into account any other information available that is relevant to the assessment referred to in paragraph 4.

6. The data and information referred to in paragraph 5, points (a) to (d), shall be provided by Member States in accordance with paragraph 9.

7. A category of machinery or related product shall be included in Annex I, Part A, if, according to the assessment referred to in paragraph 4, and taking into account the available information, including the data referred to in paragraph 5, it presents a serious inherent potential risk, and one or more of the following conditions is fulfilled:

(a) there is a lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;

(b) residual risks exist, including those which, according to the manufacturer, could be reduced by particular training or personal protective equipment, and the data and information referred to in paragraph 5, demonstrate the recurrence of similar serious or fatal accidents or damage to health in connection with those residual risks;

(c) data and information exist which according to the Commission demonstrate recurring wrongful application of the relevant harmonised standards or common specifications and for which the market surveillance activities that were carried out have not led to major improvements of the market situation, in a reasonable period;

(d) there is a degree of uncertainty in the existing risk assessment methods related to new categories of machinery or technologies.

Any other category of machinery or related product that, according to that assessment, presents a serious inherent potential risk but does not fulfil one or more of the conditions in points (a) to (d) shall be included in Annex I, Part B.

8. 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 those concerns and provide reasons in support thereof.

The Commission shall conduct the assessment referred to in paragraph 4 immediately after being informed by a Member State.

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

9. By 14 July 2025, and every five years thereafter, Member States shall provide the data and information referred to in paragraph 5, including information to the effect that none of the events referred to in paragraph 5 has occurred, for every category of machinery or related products which is included in Annex I or which is not included in Annex I where that non-inclusion is a cause of concern for the Member State.

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

When adopting those implementing acts, the Commission shall issue 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 48(3).

The first such implementing act shall be adopted not later than 14 July 2024.

11. If necessary after the Commission report referred to in Article 53(3), the Commission shall adopt delegated acts in accordance with Article 47 to supplement paragraph 5 of this Article by specifying the obligations of Member States to provide data and information required pursuant to this Article through the establishment of a common methodology concerning the data and information to be collected, including the methods for their collection and compilation, and the procedures for their transmission, as well as the relevant definitions, in order to ensure that sufficient and comparable data is available for the Commission to carry out the assessment referred to in paragraph 4.

Article 7

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 47 to amend Annex II in the light 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.

3. 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 8

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 it meets the relevant essential health and safety requirements set out in Annex III.

Article 9

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 Union harmonisation legislation that is more specific than this Regulation, this Regulation shall not apply to that product 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 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 machinery or a related product on the market or putting it into service, manufacturers shall draw up the technical documentation set out in Annex IV, Part A and carry out the relevant conformity assessment procedure referred to in Article 25 or have it carried out.

Where compliance of machinery or a 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 21 and affix the CE marking in accordance with Article 24.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity at the disposal of the market surveillance authorities for at least 10 years after the machinery or the related product has been placed on the market or put into service. Where relevant, the source code or the programming logic included in the technical documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them 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 in order that machinery or related products that are part of a series production remain in conformity with this Regulation. Adequate account shall be taken of changes in the production process or in the design or characteristics of the machinery or related product, and changes in the harmonised standards, in other technical specifications, or in the common specifications referred to in Article 20 by reference to which the conformity of the machinery or related product is declared.

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 product 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 or related product model, series or type, the year of construction, namely the year in which the manufacturing process was completed, and any batch or serial number or other element allowing its identification that exists, or, where the size or nature of the machinery or related product does not allow this, 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, and the postal address and 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 product. 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 the 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, or, where that is not possible, on its 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 for at least 10 years after the placing on the market of the machinery or related product.

However, at the 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 machinery or a related product intended for non-professional users or that 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 is essential for putting the machinery or related product into service and for using it in a safe way.

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

8. Manufacturers shall ensure that the machinery or related product is accompanied by the EU declaration of conformity set out in Annex V, Part A or, alternatively, manufacturers shall provide the internet address or machine-readable code where that EU declaration of conformity can be accessed in the instructions for use and the information set out in Annex III.

Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the machinery or related product and in any event for at least 10 years after the placing on the market or the putting into service of the machinery or related product.

9. Manufacturers who consider or have reason to believe that machinery or a 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 to the health or safety of persons, and, where appropriate, domestic animals or to property, and, where applicable, to the environment, 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 in which they put it 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 that authority with all the information and documentation, in paper or digital format, 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 11

Obligations of manufacturers of partly completed machinery

1. When placing 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 partly completed machinery on the market, manufacturers shall draw up the technical documentation set out in Annex IV, Part B.

Where compliance of partly completed machinery with the relevant essential health and safety requirements set out in Annex III has been demonstrated in the technical documentation set out in Annex IV, Part B, manufacturers shall draw up the EU declaration of incorporation in accordance with Article 22.

3. Manufacturers shall keep the technical documentation and the EU declaration of incorporation at the disposal of the market surveillance authorities for at least 10 years after the partly completed machinery has been placed on the market. Where relevant, the source code or the programming logic included in the technical documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them to be able to check compliance with the relevant essential health and safety requirements set out in Annex III.

4. Manufacturers shall ensure that procedures are in place for partly completed machinery that is part of a series production to remain in conformity with this Regulation. Adequate account shall be taken of 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 20, by reference to which the conformity of the partly completed machinery is declared or verified.

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, namely the year in which the manufacturing process was completed, model and series or type and any batch or serial number or other element allowing its identification that exists, or, where the size or nature of the partly completed machinery does not allow this, 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, and 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 machinery and by market surveillance authorities.

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

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, or, where that is not possible, on its 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 at least 10 years after the placing on the market of the partly completed machinery.

However, at the request of the person who incorporates the partly completed machinery at the time of purchase, 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, and legible.

8. Manufacturers shall ensure that the partly completed machinery is accompanied by the EU declaration of incorporation set out in Annex V, Part B or, alternatively, manufacturers shall provide the internet address or machine readable code where that EU declaration of incorporation can be accessed in the assembly instructions set out in Annex XI.

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

9. Manufacturers who consider or have reason to believe that 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 relevant 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 that authority 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 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 relevant essential health and safety requirements presented by the partly completed machinery, which they have placed on the market.

Article 12

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 11(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 at least 10 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, 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 13

Obligations of importers of machinery and related products

1. Importers shall place only compliant machinery or related products on the market.

2. Before placing machinery or a related product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 25 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation set out in Annex IV, Part A, that the machinery or related product bears the CE marking referred to in Article 23 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5), (6) and (8).

Where an importer considers or has reason to believe that machinery or a 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, to 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, and 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 the information referred to in Article 10(7).

5. Importers shall ensure that, while the machinery or related product is under their responsibility, the storage or transport conditions do not jeopardise conformity with the essential health and safety requirements set out in Annex III.

6. When deemed appropriate with regard to the risks presented by machinery or a related product, importers shall, in order to protect the 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 product recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that machinery or a 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, to 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 at least 10 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 Annex IV, Part A, can be made available to those authorities upon request.

Where relevant, the source code or the programming logic included in the technical documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them 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 that authority with all the information and documentation, in paper or digital format, necessary to demonstrate conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority. Importers shall cooperate with that authority, at its request, on any action taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment presented by machinery or related products which they have placed on the market.

Article 14

Obligations of importers of partly completed machinery

1. Importers shall place only compliant partly completed machinery on the market.

2. Before placing partly completed machinery on the market, importers shall ensure that the manufacturer has drawn up the technical documentation set out in Annex IV, Part B, that the partly completed machinery is accompanied by the required documents and that the manufacturer has complied with the requirements set out in Article 11(5), (6) and (8).

Where an importer considers or has reason to believe that 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, and 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 by the market surveillance authorities.

4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions referred to in Article 11(7).

5. Importers shall ensure that, while the partly completed machinery is under their responsibility, the storage or transport conditions 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 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 relevant 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 at least 10 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 Annex IV, Part B can be made available to those authorities upon request.

8. Importers shall, further to a reasoned request from a competent national authority, provide that authority 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. Importers shall cooperate with that authority, at its request, on any action taken to eliminate the risks as regards the relevant essential health and safety requirements presented by a partly completed machinery, which they have placed on the market.

Article 15

Obligations of distributors of machinery and related products

1. When making machinery or a related product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making machinery or a 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 referred to in Article 10(8);

(c) the machinery or related product is accompanied by the instructions for use and the information referred to 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;

(d) the manufacturer and the importer have complied with the requirements referred to in Article 10(5) and (6) and Article 13(3) respectively.

3. Where a distributor considers or has reason to believe that machinery or a 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 presents a risk to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment, the distributor shall inform the manufacturer or the importer as well as the market surveillance authorities to that effect.

4. Distributors shall ensure that, while machinery or a related product is under their responsibility, the storage or transport conditions do not jeopardise conformity with the essential health and safety requirements set out in Annex III.

5. Distributors who consider or have reason to believe that machinery or a 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, to 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 that authority 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 action taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, to the environment presented by machinery or a related product which they have made available on the market.

Article 16

Obligations of distributors of partly completed machinery

1. When making partly completed machinery available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making partly completed machinery available on the market, distributors shall verify that:

(a) the partly completed machinery is accompanied by the EU declaration of incorporation referred to in Article 11(8);

(b) the partly completed machinery is accompanied by the assembly instructions referred to in Article 11(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 referred to in Article 11(5) and (6) and Article 14(3) respectively.

3. Where a distributor considers or has reason to believe that 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 as well as the market surveillance authorities to that effect.

4. Distributors shall ensure that, while a partly completed machinery is under their responsibility, the storage or transport conditions do not jeopardise conformity with the relevant essential health and safety requirements set out in Annex III.

5. Distributors who consider or have reason to believe that 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 the relevant 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 that authority 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 action taken to eliminate the risks as regards the essential health and safety requirements presented by partly completed machinery which they have made available on the market.

Article 17

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered to be a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer set out in Articles 10 and 11, where that importer or distributor places a product within the scope of this Regulation on the market under its name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements might be affected.

Article 18

Other cases in which obligations of manufacturers apply

A natural or legal person that carries out a substantial modification of machinery or a related product shall be considered to be 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 an impact on the safety of only machinery or a related product that is part of an assembly of machinery, for that affected machinery or related product, as demonstrated in the risk assessment.

The person who carries out the substantial modification shall in particular, but 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 25 (2), (3) and (4) of this Regulation.

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

Article 19

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. In order to be able to comply with the obligation in paragraph 1, economic operators shall retain the information referred to in that paragraph for at least 10 years after they supplied or were supplied with the products within the scope of this Regulation.

CHAPTER III

CONFORMITY OF PRODUCTS WITHIN THE SCOPE OF THIS REGULATION

Article 20

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 may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential health and safety requirements set out in Annex III for products within the scope of this Regulation.

Those implementing acts shall only be adopted where the following conditions are fulfilled:

(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) 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:

  (i) the request has not been accepted; or

  (ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or

  (iii) the harmonised standards do 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 has been 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 48(3).

4. Before preparing the draft implementing act referred to in paragraph 3, 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 have been fulfilled.

5. When preparing the draft implementing act referred to in paragraph 3, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.

6. A product within the scope of this Regulation which is in conformity with the common specifications established by 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.

7. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing 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 the implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements as those covered by that harmonised standard.

8. 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 by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.

9. Machinery and related products that have been certified or for which a statement of conformity has been issued under a cybersecurity certification scheme adopted in accordance with Regulation (EU) 2019/881 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 insofar as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.

Article 21

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 Annex V, Part A, and shall contain the elements specified in the relevant modules set out in Annexes VI, VIII, IX, and X. It shall be continuously updated and 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 machinery or a related product is subject to more than one Union legal act that requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such acts. That declaration shall contain the identification of the Union legal 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 22

EU declaration of incorporation of partly completed machinery

1. The EU declaration of incorporation shall state that the fulfilment of the relevant 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 Annex V, Part B. It shall be continually updated and 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 partly completed machinery is subject to more than one Union legal act requiring an EU declaration of conformity, the EU declaration of incorporation shall include a sentence declaring the conformity with such acts. That declaration shall contain the identification of the Union legal 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 23

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 24

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 a related product is assessed in accordance with the conformity assessment procedure referred to in Article 25(2), points (a), (b) and (c) and in Article 25(3), points (b), (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 that 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 25

Conformity assessment procedures for machinery and related products

1. The manufacturer or the natural or legal person referred to in Article 18 shall apply one of the conformity assessment procedures referred to in paragraphs 2, 3 and 4.

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 18 shall apply one of the following procedures:

(a) EU type-examination (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 X.

3. Where the category of machinery or related product is listed in Annex I, Part B, the manufacturer or the natural or legal person referred to in Article 18 shall apply one of the following procedures:

(a) internal production control (module A) set out in Annex VI;

(b) EU type-examination (module B) set out 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 (module H) set out in Annex IX;

(d) conformity based on unit verification (module G) set out in Annex X.

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

Where the category of machinery or related product is listed in Annex I, Part B, and the machinery or related product was not designed and constructed in accordance with the harmonised standards or common specifications specific to that category of machinery or related product covering all the relevant essential health and safety requirements for that category of machinery or related product, the manufacturer, including a natural or legal person referred to in Article 18, shall apply one of the procedures referred to in points (b), (c) or (d) of this paragraph.

4. Where the category of machinery or related product is not listed in Annex I, the manufacturer, including a natural or legal person referred to in Article 18, shall apply the internal production control procedure (module A) set out in Annex VI.

5. 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 26

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 27

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 32.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body, as defined in Regulation (EC) No 765/2008 in accordance with that Regulation.

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 28. In addition, that body shall have arrangements in place 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 28

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, nor shall it offer or provide 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 29

Information obligation of notifying authorities

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

The Commission shall make that information publicly available.

Article 30

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 shall have legal personality.

3. A conformity assessment body shall be a third-party body that is independent of the organisation or of the machinery or related product that 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 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 shall it 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 the 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 X and in relation to which it has been notified, regardless of 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 or related product 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 20, 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 X, 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 42 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 31

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 30 insofar as the applicable harmonised standards cover those requirements.

Article 32

Use of subcontractors and subsidiaries 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 30 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 X.

Article 33

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 X 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 30.

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 30.

Article 34

Notification procedure

1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 30.

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 or categories 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 33(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 30.

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 33(2), or within two months of the notification where it includes documentary evidence referred to 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 35

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 36

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 30, or that it is failing to fulfil its obligations as set out in Article 38 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 37

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 48(2).

Article 38

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 X.

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 20 have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective actions and shall not issue an EU-type examination certificate, adopt a quality system approval decision or issue a unit verification certificate.

4. Where, in the course of the monitoring of conformity, following the adoption of an approval decision, in accordance with Annex IX, a notified body finds that machinery or a 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.

Where corrective actions are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any approval decisions, as appropriate.

Article 39

Appeals against decisions of notified bodies

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

Article 40

Information obligation of notified bodies

1. A notified body shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of an EU type-examination certificate, quality system approval decision or unit verification certificate;

(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 41

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 42

Coordination of notified bodies

The Commission shall ensure the establishment and good functioning of appropriate coordination and cooperation between bodies notified under this Regulation 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 43

Procedure at national level for dealing with products within the scope of this Regulation 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 property, and, where applicable, to 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, minimise the risk specified by the market surveillance authorities 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 products within the scope of this Regulation concerned that the economic operator has made available on the market, throughout the Union.

4. Where the relevant economic operator does not take the corrective action referred to in paragraph 1, second subparagraph, within the specified period or where the non-compliance, referred to in paragraph 1, second subparagraph, 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 it available on the market is prohibited or restricted. In such cases, the market surveillance authorities shall ensure 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) the 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 20(1);

(c) shortcomings in the common specifications referred to in Article 20(6).

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 product within the scope of this Regulation concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in 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 to be justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the product, are taken in respect of the product within the scope of this Regulation concerned without delay.

Article 44

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 43(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 legal acts, 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.

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

3. Where the national measure is considered to be justified and the non-compliance of the product within the scope of this Regulation is attributed to shortcomings in the harmonised standards referred to in Article 43(5), point (b), of this Regulation or common specifications referred to in Article 43(5), point (c), of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or in Article 20(8) of this Regulation respectively.

Article 45

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

1. Where, having carried out an evaluation under Article 43(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, to 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, commensurate with the nature of the risk.

2. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products within the scope of this Regulation 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 about the product which presents a risk, as referred to in paragraph 1. 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 48(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 48(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 46

Formal non-compliance

1. Without prejudice to Article 43, where a Member State makes one of the following findings with regard to machinery or a 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 24 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 24(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 13(3) is absent, false or incomplete;

(g) any other administrative requirement provided for in Article 10 or Article 13 is not fulfilled.

2. Without prejudice to Article 43, 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 11(5) or Article 14(3) is absent, false or incomplete;

(d) any other administrative requirement provided for in Article 11 or Article 14 is not fulfilled.

3. Where the non-compliance referred to in paragraphs 1 and 2 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product within the scope of this Regulation concerned 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 47

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 6(2), 6(11) and 7(2) shall be conferred on the Commission for a period of five years from 13 July 2023. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 6(2), 6(11) and 7(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. 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.

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 6(2), 6(11) or 7(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 48

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.

Where the committee delivers no opinion regarding the draft implementing act referred to in Article 20(3), Article 5(4), third subparagraph, 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 legal act.

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 49

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 competent national authority that originally provided the information.

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 shall it affect 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 bilateral or multilateral confidentiality agreements and arrangements when those agreements and arrangements ensure that any exchange of information is in accordance with applicable Union law.

Article 50

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 14 October 2026, 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 51

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 14 January 2027.

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 XII.

Article 52

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 14 January 2027. However, Chapter VI of this Regulation shall apply, from 13 July 2023, *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 53

Evaluation and review

1. By 14 July 2028 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 6, 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.

3. By 14 July 2026 and every five years thereafter, the Commission shall submit a specific report on the assessment of Article 6(4) and (5) of this Regulation to the European Parliament and to the Council. The reports shall be made public.

The Commission shall include in its reports the following:

(a) a summary of data and information provided by Member States in accordance with Article 6(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 6(4).

In the reports, the Commission shall assess the appropriateness and availability of data and information provided by Member States, including its sufficiency and suitability for the purposes of making comparisons, identifying any shortcomings, necessary to ensure effective functioning and enforcement of Article 6.

Article 54

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 14 January 2027.

However, the following Articles shall apply from the following dates:

(a) Articles 26 to 42 from 14 January 2024;

(b) Article 50(1) from 14 October 2023;

(c) Article 6(7) and Articles 48 and 52 from 13 July 2023;

(d) Article 6(2) to (6), (8) and (11) and Articles 47 and 53(3) from 14 July 2024.

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

Done at Strasbourg, 14 June 2023.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	J. ROSWALL

ANNEX I

CATEGORIES OF MACHINERY OR RELATED PRODUCTS TO WHICH ONE OF THE PROCEDURES REFERRED TO IN ARTICLE 25(2) AND (3) SHALL BE APPLIED

PART A

Categories of machinery or related products to which a procedure referred to in Article 25(2) shall be applied:

1. Removable mechanical transmission devices including their guards.

2. Guards for removable mechanical transmission devices.

3. Vehicle servicing lifts.

4. Portable cartridge-operated fixing and other impact machinery.

5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.

6. Machinery that has embedded 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 of those systems.

PART B

Categories of machinery or related products to which one of the procedures referred to in Article 25(3) 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 work-pieces, 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.

14. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than 3 m.

15. Protective devices designed to detect the presence of persons.

16. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of this Part.

17. Logic units to ensure safety functions.

18. Roll-over protective structures (ROPS).

19. Falling-object protective structures (FOPS).

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, Part B.

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.

19. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions.

20. Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, includingplant protection products, and filters for such filtration systems.

ANNEX III

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

PART A

Definitions

For the purposes of this Annex, the following definitions apply:

(a) 'hazard' means a potential source of injury or damage to health;

(b) 'danger zone' means any zone within and/or around machinery or a 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 machinery or a 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 machinery or a 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 machinery or a related product in accordance with the information provided in the instructions for use;

(i) 'reasonably foreseeable misuse' means the use of machinery or a related product in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.

PART B

General principles

1. The manufacturer of machinery or a related product shall ensure that a risk assessment is carried out in order to determine the essential 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;

   (b) identify the hazards that may be generated by the machinery or related product and the associated hazardous situations;

   (c) estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence;

   (d) evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Regulation;

   (e) 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 might arise during the lifecycle of the machinery or related product that are foreseeable at the time of placing 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 machinery as defined in Article 3, point 1, point (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 products 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 products. 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 health and safety requirements. When machinery or a 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 products 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 insofar as 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) Machinery or related products shall be designed and constructed so that they are fit for their 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 machinery or a 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) Machinery or related products 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) Machinery or related products 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 machinery or related products, or products used or created during its use, shall not endanger the health and safety of persons. In particular, where fluids are used, machinery or related products shall be designed and constructed to prevent risks due to filling, use, recovery or draining.

1.1.4. *Lighting*

Machinery or related products 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.

Machinery or related products 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 machinery or a related product to facilitate its handling*

Machinery or a 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 machinery or a 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 machinery or a 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;

(b) avoiding the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity;

(c) providing enough space for movements of the parts of the operator's body;

(d) avoiding a machine-determined work rate;

(e) avoiding monitoring that requires lengthy concentration;

(f) adapting the human-machine interface to the foreseeable characteristics of the operators, including with respect to machinery or a related product with intended fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy;

(g) where relevant, adapting machinery or a 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 essential 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 essential 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 are to be established as part of the risk assessment performed by the manufacturer and no modifications are 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 could 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 products with fully or partially self-evolving behaviour or logic that are 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;

(b) 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;

(c) it shall be possible at all times to correct the machinery or related product in order to maintain its inherent safety.

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 could 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 could 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 machinery or related products or partly completed machinery, or a combination thereof.

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 or hand-guided machinery or related products.

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 machinery or a related product or parts of machinery or a related product designed to work together, the machinery or a related product 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 product 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 or related product 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 machinery's or related 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 product 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 product shall not be prevented from stopping if the stop command has already been given;

(d) no moving part of the machinery or related product or piece held by the machinery or related product 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 product.

If the shape of the machinery or related product 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 products 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 or a related product 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 hazardous situations and the psychological stress that may be caused by the interaction with the machinery 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 those guards are closed; and

(b) gives a stop command whenever those guards 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 machinery or related products have an electricity supply, they 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 machinery or related products. However, the obligations concerning conformity assessment and the placing on the market or putting into service of machinery or related products with regard to electrical risks are governed solely by this Regulation.

1.5.2. *Static electricity*

Machinery or related products 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 machinery or related products are powered by source of energy other than electricity, they 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*

Machinery or related products 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*

Machinery or related products 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.

Machinery or related products 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*

Machinery or related products 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 products.

1.5.9. *Vibrations*

Machinery or related products 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 machinery or related products 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*

Machinery or related products 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 machinery or related products shall be designed and constructed in such a way as to prevent any accidental radiation;

(b) laser equipment on machinery or related products 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 machinery or related products shall be such that no health risk is created by laser radiation.

1.5.13. *Emissions of hazardous materials and substances*

Machinery or related products 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 hazard 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*

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 product 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*

Machinery or related products 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 products, a connecting device for mounting diagnostic fault-finding equipment shall be provided.

Automated machinery or related product 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 or related products 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 or related product.

In the case of machinery or related products 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 an emergency rescue of the persons is possible.

1.6.3. *Isolation of energy sources*

Machinery or related products 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 or related product shall be designed and constructed in such a way that it is possible to clean internal parts, which have contained dangerous substances or mixtures without entering them; any necessary unblocking shall also be possible from the outside. If it is impossible to avoid entering the machinery or related product, 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 machinery or a 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 unsupervised machinery or a 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 machinery or a 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 legal acts 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 machinery or related products*

In addition to the marking requirements in Article 10 and 24, machinery or related products shall be marked visibly, legibly and indelibly.

Machinery or related products covered by chapters 2 to 6 of this Annex shall also be marked according to the additional requirements set out in those chapters.

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

Machinery or related products shall also bear full information relevant to their type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.

Where machinery or a related product part is 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 for use shall be drawn up as set out below.

By way of exception to Article 10(7), the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or its 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

(a) 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;

(b) In the case of machinery or related products 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 its 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 the ways in which the machinery or related product must 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 μPa);

(iii) 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 technically comparable machinery or for a technically comparable related product, which is representative of the machinery or related product to be produced.

In the case of very large machinery or a 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 20(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 m from the surface of the machinery or related product and at a height of 1,6 m 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 legal acts lay 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;

(v) information on the necessary precautions, devices and means for the immediate and gentle rescue of persons;

(w) where machinery or related products are 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;

(x) where the design of machinery or related products 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 technically comparable machinery or a technically comparable 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

Machinery and related products for foodstuffs, machinery and related products for cosmetics or pharmaceutical products, portable hand-held or hand-guided machinery and related products, portable fixing and other impact machinery and related products, machinery and related products for working wood and material with similar physical characteristics and machinery and related products for plant protection products application shall meet all the essential health and safety requirements set out 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 products 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 laid 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 and 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, and 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 products 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 products 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 or water intended for human consumption, cosmetics or pharmaceutical products; where necessary, machinery or related products 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 machinery or related products for foodstuffs and machinery or related products for 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 products 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 products 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 or hand-guided machinery or related products:

(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 product 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 20(3) cannot be applied, the vibration data shall be measured using the most appropriate measurement code for the machinery or related product.

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 products 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 products 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 non-fully automated machinery or a related product, that machinery or related product 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. *For the purposes of section 2.4., the following definition applies:*

'Machinery or related products 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(1), of Regulation (EC) No 1107/2009 of the European Parliament and of the Council [1].

[1] 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 products for plant protection products application shall ensure that an assessment is carried out of the risks of unintended exposure of the environment to plant protection products, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1.

Machinery or related products for plant protection products 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 products can be operated, adjusted and maintained without unintended exposure of the environment to plant protection products.

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 plant protection products 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 plant protection products and to ensure easy and complete emptying, while preventing spillage of plant protection products and avoiding the contamination of the water source during such operations.

2.4.5. *Application of plant protection products*

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 plant protection products

The machinery or related product shall be designed and constructed to ensure that the plant protection product is deposited on target areas, to minimise losses to other areas and to prevent drift of plant protection products 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 plant protection products 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 the plant protection product 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 plant protection product 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 the plant protection product 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 the plant protection product;

(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 plant protection products that may cause incorrect functioning of the machinery or related product;

(g) an indication that the operator should keep updated the name of the plant protection product 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 Council [2];

(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 products presenting risks due to their mobility shall meet all the essential health and safety requirements set out in this chapter (see General Principles, point 4).

[2] 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).

3.1. **General**

3.1.1. *For the purposes of this section, the following definitions apply:*

(a) 'Machinery or related products presenting risks due to their mobility' means:

(i) machinery or related products, the operation of which requires either mobility while working, or continuous or semi continuous movement between a succession of fixed working locations; or

(ii) machinery or related products which are operatedwithout 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 machinery or a 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 mobile machinery which 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;

(d) 'Supervisor' means a person responsible for the supervision of autonomous mobile machinery;

(e) 'Supervisory function' means remote non permanent surveillance of 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 reasonably foreseeable conditions of use. Where necessary, appropriate devices shall be provided to remedy risks due to inadequate direct vision.

Machinery or a 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 risk of roll or tip over 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 machinery. The supervisory function shall only allow actions to stop and to start remotely the machinery or related product 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 machinery 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 machinery 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 the intervention of the supervisor.

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.

Remote-controlled machinery or related products 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 or related product 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 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 products shall comply, with one or both where necessary according to the risk assessment, of the following conditions:

(i) it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;

(ii) 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 the health and safety of persons or domestic animals or to the safe operation of the machinery or related product.

The movements of mobile machinery or a related product connected with one or more trailers or towed equipment, including autonomous mobile machinery or a related product connected with one or more trailers or towed equipment, shall not give rise to risks for persons, domestic animals or to 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 machinery 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*

Machinery or related products shall be designed, constructed, and where appropriate placed on a 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 do not need to 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 a 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 the 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 the 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.

Machinery or related products 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 or related products, including autonomous mobile machinery or related products, 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 other machinery or related products 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 their height, mobile machinery or related products 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 products 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 products 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 products 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 products 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 a related product for the operation of signals.

Remote-controlled machinery or related products 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 shall apply to machinery or related products, 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 machinery is not directly visible to the driver.

Machinery or related products 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*

(1) 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).

(2) In addition, where appropriate, the following shall be shown legibly and indelibly on all machinery or related products:

(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 product in question or those established on the basis of measurements taken in respect of technically comparable machinery or related products which are representative of the machinery or related products to be produced.

Where harmonised standards or common specifications adopted by the Commission in accordance with Article 20(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 machinery or a 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 RISKS DUE TO LIFTING OPERATIONS

Machinery or related products presenting risks due to lifting operations shall meet all the relevant essential health and safety requirements set out in this chapter (see General Principles, point 4).

4.1. **General**

4.1.1. *For the purposes of section 4.1., the following definitions apply:*

(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 related product or lifting accessory and the maximum working load marked on the machinery or related product or lifting accessory;

(e) 'Static test' means the test during which the machinery or related product 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 the machinery or related product 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 or related products running on guide rails and rail tracks

Machinery or related products 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 related products, including 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 related products, including 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 related products, including 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 related products, including lifting accessories: 1,5;

(b) other machinery or related products: 1,25.

Machinery or related products 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 or related product 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 points (a) to (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 products 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 products 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 machinery;

(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 products 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 with guard locking 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 related products, including 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 related products, including 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 or related products ready to be put into service.

Where the machinery or related products 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 products or their 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 products with a maximum working load of not less than 1 000 kg 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:

(a) identification of the material where this information is needed for safe use;

(b) 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 or related products*

The maximum working load shall be prominently marked on the lifting machinery or related product. 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 or related product, 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 or related products 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 or related products*

Lifting machinery or related products shall be accompanied by instructions for use containing information on:

(a) the technical characteristics of the lifting machinery or related product, 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 or related products, which are not assembled on the premises of the manufacturer in the form in which they are to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before they are first put into service.

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

Machinery or related products intended for underground work shall meet all the essential health and safety requirements set out 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 products, which comprises highly flammable parts.

The braking system of machinery or related products 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 products 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 products presenting particular risks due to the lifting of persons shall meet all the relevant essential health and safety requirements set out 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 products intended for the lifting of persons and shall, as a general rule, be doubled. Machinery or related products 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 product 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 products 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

Technical documentation

PART A

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;

(b) 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;

(c) design and manufacturing drawings and schemes of the machinery or related product 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 machinery or related product;

(e) the references of the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(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;

(f) 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 requirement;

(g) 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;

(h) 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;

(i) a copy of the instructions for use and the information set out in section 1.7.4 of Annex III;

(j) where appropriate, the EU declaration of incorporation for partly completed machinery set out in Annex V, Part B, and the assembly instructions set out in Annex XI;

(k) where appropriate, copies of the EU declarations of conformity of machinery or related products as well as any product covered by other Union harmonisation legislation incorporated into the machinery or related product;

(l) 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;

(m) 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;

(n) for sensor-fed, remotely-driven, or autonomous machinery or related products, 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;

(o) 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.

PART B

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 relevant 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;

(b) 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 20(1) or common specifications adopted by the Commission in accordance with Article 20(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, descriptions of the other technical specifications that have been applied in order to meet each applicable essential health and safety requirement;

(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;

(h) 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;

(i) a copy of the assembly instructions for the partly completed machinery set out in Annex XI;

(j) 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;

(k) 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;

(l) 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;

(m) 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.

ANNEX V

EU DECLARATION OF CONFORMITY AND EU DECLARATION OF INCORPORATION

PART A

EU declaration of conformity of machinery and related products No … [1]

The EU declaration of conformity shall contain the following particulars:

1. The machinery or related product (product, type, model, batch or serial number) or substantially modified machinery or related product.

2. Name and address of the manufacturer and, where applicable, its 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 the 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 referred to in point 5 is in conformity with the following Union harmonisation legislation.

7. References to the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that were applied, including the date of the publication of the reference to harmonised standards in the *Official Journal of the European Union* 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 were 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):

[1] It is optional for the manufacturer to assign a number to the declaration of conformity.

PART B

EU declaration of incorporation of partly completed machinery No … [2]

The declaration of incorporation shall contain the following particulars:

1. The partly completed machinery (product, type, model batch or serial number).

2. Name and address of the manufacturer and, where applicable, its 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 health and safety requirements set out in Annex III of Regulation (EU) 2023/1230 of the European Parliament and of the Council [3] are applied and fulfilled and that the relevant technical documentation was drawn-up in accordance with Annex IV, Part B, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Union harmonisation legislation.

6. References to the harmonised standards referred to in Article 20(1) or common specifications adopted by the Commission in accordance with Article 20(3) that were 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 incorporation shall specify the parts which were 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):

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[2] It is optional to assign a number to the declaration of conformity.

[3] Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1).

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 its 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 products 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 machinery or related products, individually, 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 21 and keep it, together with the technical documentation, at the disposal of the national authorities for at least 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 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.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by its authorised representative, on its behalf and under its 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 machinery or a 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 its 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, Part A;

(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, Part A, second subparagraph, points (h) and (l), 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 20(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 20(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 20(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 20(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;

(g) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;

(h) 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 the case referred to in point (c), the review may lead to a renewal of the EU type-examination 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. Where the manufacturer fails to comply with the deadlines mentioned above, 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 that 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 or issue an addition to the original 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) its 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 20(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 at least 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 its 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 products 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 all machinery or related products that are in conformity with the type described in the EU type-examination certificate and satisfy 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 at least 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 its authorised representative, on its behalf and under its 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 its 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 products 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 its quality system with the notified body of its choice, for the machinery or related products 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 described in Annex IV, Part A, points (a) to (g), (i) to (k) and (m) to (o) for one model of each category of machinery or related products intended to be manufactured.

(c) the documentation concerning the quality system; and

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

3.2. The quality system shall ensure compliance of the 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 common specifications adopted by the Commission in accordance with Article 20(3) will not be applied in full, the means, including other technical specifications, 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 technology concerned, and with knowledge of the applicable essential health and safety requirements set out in Annex III. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b), to verify the manufacturer's ability to identify the applicable essential health and safety requirements set out in Annex III 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 its 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 that body 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 at least 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 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 at least 10 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);

(b) the documentation concerning the quality system referred to in point 3.1(c);

(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 its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

ANNEX X

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 its sole responsibility that the machinery or related product, which is subject to 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.

In addition, the technical documentation shall, wherever applicable, contain at least:

(i) the elements set out in points (a) to (g) of Annex IV, Part A;

(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.

2.1. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for at least 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 at least 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, that body's identification number, to the 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 at least 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.

6. Authorised representative

The manufacturer's obligations set out in points 2.1 and 5 may be fulfilled by its authorised representative, acting on its behalf and under its responsibility, provided that those obligations are specified in the mandate.

ANNEX XI

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 the 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 the health and safety of persons and, where appropriate, domestic animals and property, and, where applicable, of 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 the ways in which the partly completed machinery must 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 the version of the assembly instructions which corresponds to the partly completed machinery model.

If the partly completed machinery is intended to be used in machinery covered by Annex III, chapters 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 XII

CORRELATION TABLE

Directive 2006/42/EC	This Regulation
Article 1	Article 2
Article 2	Article 3
Article 3	Article 9
Article 4 (1) and (2)	Article 8
Article 4 (3) and (4)	—
Article 5	Articles 10 and 11
Article 6	Article 4
Article 7	Article 20 (1)
Article 8 (1)	Articles 6 (1) and 7 (1)
Article 8 (2)	—
Article 9	—
Article 10	Article 44 (3)
Article 11	Articles 43, 44 and 45
Article 12	Article 25
Article 13	Article 11
Article 14 (and Annex XI)	Article 26 to Article 42
Article 15	Article 5
Article 16	Articles 23 and 24
Article 17	Article 46
Article 18	Article 49
Article 19	—
Article 20	—
Article 21	Article 53
Article 21 a	Article 47
Article 22	Article 48
Article 23	Article 50

Directive 2006/42/EC	This Regulation
Article 24	—
Article 25	Article 51
Article 26	—
Article 27	—
Article 28	Article 54 (first paragraph)
Article 29	Article 54 (second and third paragraphs)
Annex I - General principles and Section 1.1.1 (Definitions)	Annex III – Part A (Definitions) and Part B (General principles)
Annex I, Sections 1.1.2 - 1.1.8.	Annex III, Chapter 1
Annex I, Section 2	Annex III, Chapter 2
Annex I, Section 3	Annex III, Chapter 3
Annex I, Section 4	Annex III, Chapter 4
Annex I, Section 5	Annex III, Chapter 5
Annex I, Section 6	Annex III, Chapter 6
Annex II, Parts A and B	Annex V, Parts A and B
Annex III	—
Annex IV	Annex I
Annex V	Annex II
Annex VI	Annex XI
Annex VII, Parts A and B	Annex IV, Parts A and B
Annex VIII, when read in conjunction with Article 12 (3) (a)	Annex VI
Annex VIII (Point 3), when read in conjunction with Article 12 (3) (b)	Annex VIII
Annex IX	Annex VII
Annex X	Annex IX
Annex XI	Article 30

REGULATION (EU) 2023/1231 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 14 June 2023

on specific rules relating to the entry into Northern Ireland from other parts of the United Kingdom of certain consignments of retail goods, plants for planting, seed potatoes, machinery and certain vehicles operated for agricultural or forestry purposes, as well as non-commercial movements of certain pet animals into Northern Ireland

(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 43(2), Article 114 and Article 168(4), point (b), 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 the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) The Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community [3] (the 'Withdrawal Agreement') was concluded on behalf of the Union by Council Decision (EU) 2020/135 [4] and entered into force on 1 February 2020. The transition period referred to in Article 126 of the Withdrawal Agreement, during which Union law continued to apply to and in the United Kingdom, in accordance with Article 127 of the Withdrawal Agreement, ended on 31 December 2020.

(2) The Protocol on Ireland/Northern Ireland (the 'Protocol') forms an integral part of the Withdrawal Agreement.

(3) By virtue of the Protocol, certain provisions of Union law listed in Annex 2 thereto lay down rules applicable, in particular, to the entry into Northern Ireland from other parts of the United Kingdom of consignments of retail goods, of plants for planting, of tubers of *Solanum tuberosum* L. for planting ('seed potatoes'), and of machinery and vehicles which have been operated for agricultural or forestry purposes, as well as non-commercial movements of pet animals into Northern Ireland.

[1] Opinion of 27 April 2023 (not yet published in the Official Journal).
[2] Position of the European Parliament of 9 May 2023 (not yet published in the Official Journal) and decision of the Council of 30 May 2023.
[3] OJ L 29, 31.1.2020, p. 7.
[4] Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 1).

(4) More specifically, certain provisions of Union law listed in Annex 2 to the Protocol lay down rules which apply to the entry into Northern Ireland from other parts of the United Kingdom of consignments of certain retail goods for the purpose of public health and consumer protection, including prohibitions on imports of certain products.

(5) Regulations (EC) No 1069/2009 ([5]), (EU) 2016/429 ([6]) and (EU) 2016/2031 ([7]) of the European Parliament and of the Council lay down rules which apply to the entry into Northern Ireland from other parts of the United Kingdom of consignments of certain retail goods of animal or plant origin, of composite products, of plants for planting other than seed potatoes, of machinery and vehicles which have been operated for agricultural or forestry purposes, and of seed potatoes, for the purpose of protecting public, animal and plant health in the internal market, including requirements for individual official certificates, rates of official controls and prohibitions on imports of certain products.

(6) Regulation (EU) 2017/625 of the European Parliament and of the Council ([8]) lays down rules for official controls on all consignments of goods entering the Union from third countries to ensure that they comply with the rules referred to in Article 1(2) thereof. In particular, Article 47 of that Regulation requires certain categories of goods to be subject to official controls at border control posts when entering the Union. In this case, by virtue of the Protocol, the rules laid down in Regulation (EU) 2017/625 apply to the entry into Northern Ireland from other parts of the United Kingdom of those consignments.

(7) Council Regulation (EC) No 1005/2008 ([9]) prohibits the importation into the Union of fishery products obtained from illegal, unreported and unregulated fishing. To ensure the effectiveness of that prohibition, fishery products may only be imported into the Union provided that they are accompanied by a catch certificate and subject to appropriate checks and verifications.

(8) Regulation (EU) No 576/2013 of the European Parliament and of the Council ([10]) lays down the animal health requirements applicable to the non-commercial movement of pet dogs, cats and ferrets into Northern Ireland from other parts of the United Kingdom, as well as rules for compliance checks and the requirement for an identification document, in the form of an animal health certificate, which is to be subject to a control at a traveller's point of entry.

(9) It is appropriate to adopt specific rules which take into account the specific situation of Northern Ireland. In particular, it is appropriate to adopt specific rules relating to the entry into Northern Ireland from other parts of the United Kingdom of certain consignments of prepacked retail goods for final consumers, and of certain consignments of plants for planting other than seed potatoes, of machinery and vehicles which have been operated for agricultural or forestry purposes, and of seed potatoes for placing on the market and use in Northern Ireland, as well as non-commercial movements of pet dogs, cats and ferrets.

([5]) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

([6]) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

([7]) Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

([8]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

([9]) Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 (OJ L 286, 29.10.2008, p. 1).

([10]) Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

(10) The specific rules should take into account the responsibility of the United Kingdom to protect public health and consumers in Northern Ireland in respect of retail goods entering into Northern Ireland from other parts of the United Kingdom. It is therefore appropriate to lay down specific rules derogating from the rules laid down in certain provisions of Union law listed in Annex 2 to the Protocol and in an Annex to this Regulation, that are exclusively for the protection of public health and consumers, so as to ensure that those rules do not apply in respect of consignments of retail goods entering into Northern Ireland from other parts of the United Kingdom with a view to being placed on the market in Northern Ireland. Those provisions of Union law should continue, however, to fully apply to such retail goods directly imported into Northern Ireland from third countries other than the United Kingdom, and to their production and further processing in Northern Ireland, as they fall outside the scope of the specific rules laid down in this Regulation.

(11) It is appropriate to clarify that the provisions of Union law listed in Annex 2 to the Protocol other than those listed in an Annex to this Regulation apply with respect to consignments of retail goods entering into Northern Ireland from other parts of the United Kingdom, unless specific rules are laid down in this Regulation. Where specific rules of this Regulation apply, and there is an inconsistency between those specific rules and the provisions of Union law, those specific rules should take precedence.

(12) Furthermore, this Regulation lays down rules on written guarantees to be provided by the United Kingdom to ensure that the application of the specific rules laid down in this Regulation does not lead to an increased risk to animal or plant health on the island of Ireland, adversely affect the sanitary and phytosanitary (SPS) status of the island of Ireland, lead to an increased risk to public, animal or plant health in the internal market, lead to an increased risk that fishery products obtained from illegal, unreported or unregulated fishing are placed on the internal market, or adversely affect the level of consumer protection in the internal market or its integrity ('written guarantees').

(13) The specific rules should include special rates of official controls to be carried out on consignments of retail goods upon arrival at the SPS Inspection Facilities in Northern Ireland, as well as a requirement that such consignments be accompanied by a general certificate, once the United Kingdom has provided the written guarantees. Such specific rules should only apply once certain conditions are fulfilled, including compliance by those retail goods with Regulations (EC) No 1069/2009, (EU) 2016/429, (EU) 2016/2031 and (EU) 2017/625, a specific marking of the retail goods, and the listing of establishments for the dispatch and reception of those retail goods, as well as the construction of SPS Inspection Facilities in Northern Ireland in accordance with the time period laid down in this Regulation, and, in relation to fishery products, the respect of the notion of illegal, unreported and unregulated fishing as defined by the Union in its application of Regulation (EC) No 1005/2008, without imposing on the United Kingdom an obligation to apply the same certification requirements and related procedures as laid down in that Regulation.

(14) Furthermore, it is appropriate to lay down specific rules for the entry into Northern Ireland from other parts of the United Kingdom of consignments of retail goods consisting of food, other than products of animal or plant origin or composite products, and food contact material, so that such consignments are not subject to the same certification requirements as the consignments of retail goods of animal or plant origin or composite products.

(15) In cases falling within the scope of this Regulation, where official controls involving certification and checks on retail goods entering Northern Ireland from other parts of the United Kingdom are reduced, and where it is therefore necessary to ensure that those retail goods remain in Northern Ireland and to ensure, by providing information to consumers concerning those retail goods, that they do not undermine public health and consumer protection in the internal market or its integrity, it is appropriate that specific marking rules are in place. Those specific rules should ensure such information to consumers and the traceability of those retail goods. They should also provide for different requirements for markings at box, shelf and individual product levels. The application of those specific rules should recognise the need for appropriate timeframes for marking requirements that minimise burdens and difficulties for supply chains, as well as the importance of the continued movement of retail goods within the United Kingdom consistent with Northern Ireland's position as part of the United Kingdom.

(16) It is appropriate to provide for bespoke mechanisms, for the sole purpose of allowing retail goods consisting of commodities from third countries other than the United Kingdom ('rest-of-the-world retail goods') of animal or plant origin, composite products and fishery products, to benefit from the specific rules laid down in this Regulation. First, in the case of rest-of-the-world retail goods of animal or plant origin or consisting of composite products, the appropriate mechanism would operate where the United Kingdom decides to adapt its rules within its internal legal order and in accordance with its constitutional requirements. To that end, it is necessary to lay down procedures concerning the adaptation of those rules, in the event that the United Kingdom decides to use that possibility, through a listing of commodities and their delisting mechanism, as well as other necessary safeguards. Where the United Kingdom decides to adapt its rules, it remains free to add more stringent conditions. Second, for fishery products, it is appropriate to take into account the rules of the United Kingdom which ensure that fishery products obtained from illegal, unreported and unregulated fishing are not imported into the United Kingdom.

(17) It is necessary that consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes before entering into Northern Ireland, and which are dispatched by professional operators in other parts of the United Kingdom for reception by professional operators in Northern Ireland or for immediate sale in the United Kingdom after their reception in Northern Ireland by professional operators do not present an unacceptable risk to plant health on the island of Ireland and for the internal market. Therefore, the entry of those consignments into Northern Ireland from other parts of the United Kingdom should be subject to specific rules in order to ensure that those consignments do not increase the risk to plant health on the island of Ireland, adversely affect the phytosanitary status of the island of Ireland or increase the risk to plant health in the internal market or affect its integrity.

(18) It is necessary that the entry into Northern Ireland from other parts of the United Kingdom of consignments of seed potatoes dispatched by professional operators in other parts of the United Kingdom for reception by professional operators in Northern Ireland or for immediate sale in the United Kingdom after their reception in Northern Ireland by professional operators do not present an unacceptable risk to plant health on the island of Ireland or for the internal market. Therefore, the entry of those consignments into Northern Ireland from other parts of the United Kingdom should be subject to certain specific rules in order to ensure that those consignments do not increase the risk to plant health on the island of Ireland, adversely affect the phytosanitary status of the island of Ireland or increase the risk to plant health in the internal market or affect its integrity.

(19) Due to the long history of the absence of rabies and the strict surveillance of *Echinoccoccus multilocularis* infection in the United Kingdom, as well as the stringent requirements on movements of dogs, cats and ferrets on and into its territory laid down in national law, the non-commercial movement of pet dogs, cats and ferrets entering into Northern Ireland from other parts of the United Kingdom should not increase the level of risk to animal health in Northern Ireland and on the island of Ireland, should not adversely affect the sanitary status of the island of Ireland, and should not increase the risk to public and animal health in the internal market, if such movements were subject to specific rules. Those specific rules should also include the provision of a simplified identification document and a written declaration by the owner or an authorised person that those animals will not be moved subsequently to a Member State. In addition, it is appropriate to provide that pet dogs, cats and ferrets from Northern Ireland which travel to other parts of the United Kingdom and then return directly to Northern Ireland should only be identified by a transponder.

(20) Furthermore, appropriate safeguards for the Union should be in place to ensure that the application of the specific rules laid down in this Regulation does not increase risks to animal or plant health on the island of Ireland, adversely affect the SPS status of the island of Ireland, increase the risk to public, animal and plant health in the internal market or increase the risk that fishery products originating from illegal, unreported or unregulated fishing are put on the internal market, or adversely affect the level of consumer protection in the internal market or its integrity.

(21) It is therefore appropriate to provide that the specific rules on consignments of retail goods, plants for planting other than seed potatoes, machinery and vehicles which have been operated for agricultural or forestry purposes, and seed potatoes, as well as the specific rules on the non-commercial movement of pet dogs, cats and ferrets, only start to apply where the Commission has received appropriate written guarantees from the United Kingdom and has examined whether the conditions for applying the specific rules have been fulfilled. In such an event, the Commission should be empowered to adopt implementing acts in order to lay down the operational rules necessary for the implementation of the specific rules, including the frequency of checks, model forms of certificates and plant health labels, and requirements for markings.

(22) It is appropriate to require the Commission to adopt implementing acts laying down safeguard measures to address specific problems arising in the context of the operation of the specific rules laid down in this Regulation where there is evidence that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the conditions laid down in this Regulation.

(23) In order to adequately react to non-compliance with this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of suspending the application of some or all of the specific rules laid down in this Regulation where an essential precondition for the operation of those specific rules is not or is no longer fulfilled, such as the completion of the SPS Inspection Facilities, or in the case of systemic failure by the United Kingdom to comply with the specific rules laid down in this Regulation. In such an event, it is appropriate to provide for a formal information and consultation mechanism with clear time limits within which the Commission should act.

(24) Where the specific rules laid down in this Regulation on the entry of consignments of retail goods into Northern Ireland from other parts of the United Kingdom are suspended, the rules laid down in the provisions of Union law listed in Annex 2 to the Protocol and in an Annex to this Regulation should apply again to such consignments.

(25) In order to amend the Annexes to this Regulation, in particular, to adapt the list of Union acts or parts thereof the provisions of which the specific rules derogate from, to lay down further details regarding the operation of the specific rules concerning the SPS Inspection Facilities, the listing of establishments, the monitoring mechanisms, and the marking of retail goods in accordance with appropriate criteria, and in order to allow the Commission to take suspension measures in the case of the systemic failure of the United Kingdom to comply with the specific rules laid down in this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission.

(26) In order to ensure an effective and swift reaction to any increased risk to animal, plant or public health, this Regulation should provide for the possibility for the Commission to adopt delegated acts in accordance with an urgency procedure. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([11]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(27) In order to ensure uniform conditions for the implementation of this Regulation, in particular regarding the special rates of official controls and the general certificate, including its model form, the list of commodities of animal or plant origin or composite products originating in third countries that may be used for the production of retail goods to which the specific rules laid down in this Regulation should apply, the list of flag States of the vessels which catch fishery products to which the specific rules should apply, the model form of the plant health

([11]) OJ L 123, 12.5.2016, p. 1.

label for plants for planting other than seed potatoes, for machinery and vehicles which have been operated for agricultural or forestry purposes, and for seed potatoes, the information to be included in the pet travel document and appropriate special conditions and safeguard measures to address specific problems arising in the context of the operation of the specific rules laid down in this Regulation where there is evidence that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the conditions laid down in this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([12]).

(28) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the need to ensure an effective and quick reaction to an increased risk to animal, plant or public health or consumer protection, imperative grounds of urgency so require.

(29) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(30) It is appropriate to provide for a transitional period for the application of the specific rules laid down in this Regulation on marking requirements to retail goods which are already on the market,

HAVE ADOPTED THIS REGULATION:

CHAPTER 1

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down specific rules relating to the entry into Northern Ireland from other parts of the United Kingdom of the following:

(a) certain consignments of retail goods for placing on the market in Northern Ireland for the final consumer;

(b) certain consignments of plants for planting other than seed potatoes, of machinery and vehicles which have been operated for agricultural or forestry purposes and of seed potatoes for placing on the market and use in Northern Ireland.

This Regulation also lays down specific rules relating to non-commercial movements into Northern Ireland from other parts of the United Kingdom of pet dogs, cats and ferrets.

2. By way of derogation from the provisions of Union law listed in Annex 2 to the Protocol on Ireland/Northern Ireland (the 'Protocol') and which are also listed in Annex I to this Regulation, those provisions shall not apply with respect to consignments of retail goods which enter into Northern Ireland from other parts of the United Kingdom for placing on the market in Northern Ireland and fall within the scope of Chapter 2 of this Regulation.

The provisions of Union law listed in Annex 2 to the Protocol other than those listed in Annex I to this Regulation shall apply with respect to consignments of retail goods which enter into Northern Ireland from other parts of the United Kingdom for placing on the market in Northern Ireland, unless more specific provisions are laid down in this Regulation.

3. This Regulation also lays down rules regarding the suspension of the application of the specific rules laid down in this Regulation.

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

Article 2

Definitions

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

(1) 'consignment' means a quantity of goods covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport, and, in respect of retail goods, dispatched by the same listed establishment in parts of the United Kingdom other than Northern Ireland, and delivered to the same listed establishment in Northern Ireland, and, with respect to plants for planting, including seed potatoes, and machinery and vehicles operated for agricultural or forestry purposes, dispatched by professional operators in parts of the United Kingdom other than Northern Ireland and received by a professional operator in Northern Ireland;

(2) 'retail goods' means the following goods that are delivered at distribution terminals, including terminals distributing retail goods under controlled temperatures, supermarket distribution centres, wholesale outlets and points of sale, or that are delivered directly to the final consumer, including by catering operators, at factory canteens, by institutional catering, by restaurants and by other similar food service operators and shops:

(a) products of animal or plant origin;

(b) plants other than plants intended for planting, as listed in an implementing act adopted in accordance with Article 72(1), Article 73 and Article 74(1) of Regulation (EU) 2016/2031;

(c) composite products;

(d) food other than that referred to in points (a), (b) and (c);

(e) food contact materials;

(f) ready-to-sell pet food and dog chews falling within the scope of Regulation (EC) No 1069/2009;

(3) 'placing on the market' means the holding by an operator of goods referred to in Article 1(1), points (a) and (b), of this Regulation for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer of those goods;

(4) 'final consumer' means the ultimate consumer of a retail good who will not use it as part of any business operation or activity;

(5) 'rest-of-the-world retail goods' means retail goods that consist of commodities originating in third countries other than the United Kingdom and imported into parts of the United Kingdom other than Northern Ireland;

(6) 'products of animal origin' means retail goods intended for human consumption consisting of the following:

(a) food of animal origin, including honey and blood;

(b) live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption;

(c) other animals destined to be prepared with a view to being supplied live to the final consumer;

(7) 'products of plant origin' means retail goods intended for human consumption consisting of plants and products thereof, including processed material;

(8) 'ready-to-sell pet food and dog chews' means pet food and dog chews for direct sale which are packed in ready-to-sell packages for use by the final consumer;

(9) 'composite products' means retail goods intended for human consumption containing both products of plant origin and processed products of animal origin;

(10) 'food' means food or foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([13]);

(11) 'special rate of official controls' means the rate of official controls laid down in an implementing act adopted in accordance with Article 4(3) of this Regulation;

(12) 'general certificate' means a paper or electronic document signed by the certifying officer of the competent authorities for a consignment of retail goods and providing assurance concerning compliance with the requirements laid down in this Regulation;

(13) 'prepacked' means prepared for presentation of any single item as such to the final consumer and to catering operators, consisting of the packaging into which the retail goods are put before being offered for sale, whether such packaging encloses the retail goods completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging;

(14) 'marking' means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, the packaging of a retail good or the box in which it is contained, and which cannot be easily removed or faded;

(15) 'fishery products' means fishery products as defined in Article 2, point (8), of Regulation (EC) No 1005/2008;

(16) 'establishment' means any unit of a business dispatching or receiving retail goods;

(17) 'listed establishment' means an establishment listed in accordance with Article 8 of this Regulation;

(18) 'SPS Inspection Facility' means a control post as defined in Article 3, point (38), of Regulation (EU) 2017/625 and a traveller's point of entry as defined in Article 3, point (k), of Regulation (EU) No 576/2013, both complying with the requirements laid down in those Regulations;

(19) 'SPS status' means the health status as defined in Article 4, point (34), of Regulation (EU) 2016/429 or the pest status as defined in the International Standard for Phytosanitary Measures No. 5 – Glossary of phytosanitary terms, 2022, adopted under the International Plant Protection Convention, as amended;

(20) 'dairy products' means dairy products as defined in point 7.2 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council ([14]);

(21) 'meat' means meat as defined in point 1 of Annex I to Regulation (EC) No 853/2004;

(22) 'plant health label' means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed, which cannot be easily removed or faded, issued officially or under official supervision in accordance with Article 10 or 11 of this Regulation, to accompany consignments of plants for planting, including seed potatoes, and machinery and vehicles operated for agricultural or forestry purposes;

(23) 'seed potatoes' means tubers of *Solanum tuberosum* L. for planting;

([13]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([14]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

(24) 'pet animals' means pet animals of the species listed in Part A of Annex I to Regulation (EU) No 576/2013, namely pet dogs, cats and ferrets;

(25) 'pet travel document' means a paper or electronic document issued by the competent authorities of the United Kingdom for the non-commercial movement of pet animals entering into Northern Ireland from other parts of the United Kingdom.

CHAPTER 2

SPECIFIC RULES FOR THE ENTRY INTO NORTHERN IRELAND FROM OTHER PARTS OF THE UNITED KINGDOM OF CERTAIN CONSIGNMENTS OF RETAIL GOODS WHICH ORIGINATE IN OTHER PARTS OF THE UNITED KINGDOM, OR COME FROM A MEMBER STATE, OR OF REST-OF-THE-WORLD RETAIL GOODS, FOR PLACING ON THE MARKET IN NORTHERN IRELAND

Article 3

Scope of Chapter 2

The specific rules laid down in this Chapter shall apply to the following retail goods:

(a) products of animal or plant origin, plants other than plants intended for planting, and ready-to-sell pet food and dog chews;

(b) composite products;

(c) food;

(d) food contact materials.

Article 4

Specific rules for consignments of retail goods referred to in Article 3, points (a) and (b)

1. The entry into Northern Ireland from other parts of the United Kingdom and the placing on the market in Northern Ireland of consignments of retail goods referred to in Article 3, points (a) and (b), shall be subject to specific rules on special rates of official controls and a general certificate only where all of the following conditions are fulfilled:

(a) the retail goods are prepacked and bear a marking where required in accordance with Article 6;

(b) the retail goods comply with one of the following:

(i) they originate in parts of the United Kingdom other than Northern Ireland;

(ii) they come from a Member State;

(iii) they are rest-of-the-world retail goods, consisting of commodities not subject to the animal health or plant health rules referred to in Article 1(2), points (d), (e) and (g), of Regulation (EU) 2017/625;

(iv) they are rest-of-the-world retail goods that comply with the specific rules laid down in Article 9 of this Regulation;

(v) in the case of fishery products, they were either:

— caught by a fishing vessel flying the flag of the United Kingdom and landed in parts of the United Kingdom other than Northern Ireland, or

— caught by a fishing vessel flying the flag of a Member State, or of a third country other than the United Kingdom listed in an implementing act adopted in accordance with Article 9(4) of this Regulation, and were imported into parts of the United Kingdom other than Northern Ireland;

(c) the retail goods comply with the rules laid down in Regulations (EC) No 1069/2009, (EU) 2016/429, (EU) 2016/2031 and (EU) 2017/625, and in the case of fishery products, they respect the notion of illegal, unreported and unregulated fishing as defined by the Union in its application of Regulation (EC) No 1005/2008;

(d) the retail goods are only to be placed on the market in Northern Ireland for final consumers;

(e) the retail goods are dispatched from listed establishments in parts of the United Kingdom other than Northern Ireland and received by listed establishments in Northern Ireland;

(f) the retail goods are presented for official controls at SPS Inspection Facilities of first arrival in Northern Ireland in accordance with Regulation (EU) 2017/625;

(g) written guarantees have been provided by the United Kingdom on the following:

(i) that effective official controls on consignments of retail goods at SPS Inspection Facilities of first arrival in Northern Ireland that comply with the requirements set out in Annex II to this Regulation are carried out in accordance with Regulation (EU) 2017/625; and

(ii) that official controls, evidenced through a control plan, and monitoring in accordance with the requirements set out in Part 1 of Annex III to this Regulation are carried out covering the movements of those retail goods from the SPS Inspection Facilities of first arrival in Northern Ireland to the listed establishment of destination to ensure that those consignments are solely intended for retail sale at listed establishments in Northern Ireland and will not be subsequently moved to a Member State;

those written guarantees thereby provide assurance to the Union that the special rates of official controls and the general certificate do not increase the risks to animal or plant health on the island of Ireland, do not adversely affect the SPS status of the island of Ireland, do not increase the risk to public, animal or plant health in the internal market, do not increase the risk that fishery products originating from illegal, unreported or unregulated fishing are placed on the market within the Union, and do not adversely affect the level of consumer protection in the internal market or its integrity;

(h) the Commission has adopted an implementing act in accordance with paragraph 3 of this Article, and has not taken measures in accordance with paragraph 4 of this Article or in accordance with Article 14.

2. Consignments of retail goods shall be accompanied by the general certificate referred to in paragraph 1, which shall be issued by the competent authorities of the United Kingdom. That general certificate shall certify that the retail goods in the consignment comply with the requirements laid down in paragraph 1, points (a) to (f).

3. Where the conditions concerning the written guarantees referred to in paragraph 1, point (g), of this Article are fulfilled, and taking account of Commission controls regarding compliance with the requirements for SPS Inspection Facilities set out in Annex II, the Commission may, by means of implementing acts, lay down the special rates of official controls, as well as the rules on those official controls and on the model general certificate for the consignments referred to in paragraph 1 of this Article.

The special rates of identity checks, including for compliance with paragraph 1, point (a), of this Article, and Article 5(1), point (a), shall be adapted depending on the extent to which different types of retail goods are individually marked.

Where the marking requirements laid down in Article 6(1), point (b), are complied with, the special rate of identity checks shall be reduced to 8 % of all consignments.

Where the marking requirements laid down in Article 6(1), point (c), are complied with, the special rate of identity checks shall be reduced to 5 % of all consignments.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

4. The Commission shall monitor the application by the United Kingdom of the specific rules on special rates of official controls on consignments and the general certificate referred to in paragraphs 1 and 2.

Where there is evidence, such as a Union inspection report, data on trade volumes on wine products, an audit, or a notification under the information management system for official controls referred to in Article 131 of Regulation (EU) 2017/625 (IMSOC) or under the Organic Farming Information System made available by the Commission in accordance with Article 43 of Regulation (EU) 2018/848 of the European Parliament and of the Council ([15]) (OFIS), that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the conditions referred to in paragraph 1, points (a) to (g), of this Article, the Commission shall, after having duly informed and consulted with the United Kingdom, adopt an implementing act laying down appropriate special conditions and measures, including temporary or permanent restrictions on the application of the specific rules to certain consignments or establishments, or amending the implementing act adopted in accordance with paragraph 3 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3).

5. The competent authorities of the United Kingdom may decide not to collect fees or charges for the official controls on the retail goods referred to in paragraph 1.

Article 5

Specific rules for consignments of retail goods referred to in Article 3, points (c) and (d)

1. The entry into Northern Ireland from other parts of the United Kingdom and the placing on the market in Northern Ireland of consignments of retail goods referred to in Article 3, points (c) and (d), shall be subject to specific rules on special rates of official controls and a general certificate only where all of the following conditions are fulfilled:

(a) the retail goods are prepacked and bear a marking where required in accordance with Article 6;

(b) the retail goods comply with one of the following:

(i) they originate in parts of the United Kingdom other than Northern Ireland;

(ii) they come from a Member State;

(iii) they are rest-of-the-world retail goods consisting of commodities not subject to the animal health or plant health rules referred to in Article 1(2), points (d), (e) and (g), of Regulation (EU) 2017/625 or the rules relating to fishery products laid down in Regulation (EC) No 1005/2008;

(c) the retail goods are only to be placed on the market in Northern Ireland for final consumers;

(d) the retail goods are dispatched from listed establishments in parts of the United Kingdom other than Northern Ireland and received by listed establishments in Northern Ireland;

(e) the retail goods are presented for official controls at the SPS Inspection Facilities of first arrival in Northern Ireland in accordance with Regulation (EU) 2017/625;

(f) written guarantees have been provided by the United Kingdom on the following:

(i) that effective official controls on consignments of retail goods at SPS Inspection Facilities of first arrival in Northern Ireland that comply with the requirements set out in Annex II to this Regulation are carried out in accordance with Regulation (EU) 2017/625; and

([15]) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

(ii) that official controls, evidenced through a control plan, and monitoring in accordance with the requirements set out in Part 1 of Annex III to this Regulation are carried out covering the movements of those retail goods from the SPS Inspection Facilities of first arrival in Northern Ireland to the listed establishments of destination to ensure that those consignments are solely intended for retail sale at establishments in Northern Ireland and will not be subsequently moved to a Member State;

those written guarantees thereby provide assurance to the Union that the special rates of official controls and the general certificate do not increase the risks to public health in the internal market, and do not adversely affect the level of consumer protection in the internal market or its integrity;

(g) the retail goods are accompanied by a general certificate which complies with the model laid down in an implementing act adopted in accordance with Article 4(3);

(h) the Commission has adopted an implementing act in accordance with Article 4(3) and has not taken measures in accordance with Article 4(4) and paragraph 2 of this Article or in accordance with Article 14.

2. The Commission shall monitor the application by the United Kingdom of the conditions referred to in paragraph 1 for the entry into Northern Ireland from other parts of the United Kingdom of those consignments and their placing on the market in Northern Ireland.

Where there is evidence, such as a Union inspection report, an audit, or a notification under IMSOC or OFIS, that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the conditions referred to in paragraph 1, points (a) to (g), of this Article, the Commission shall, after having duly informed and consulted with the United Kingdom, adopt an implementing act laying down appropriate special conditions and measures, or amending the implementing act adopted in accordance with Article 4(3).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3).

3. The competent authorities of the United Kingdom may decide not to collect fees or charges for the official controls on the retail goods referred to in paragraph 1.

Article 6

Marking of retail goods

1. Retail goods shall be marked in accordance with the following requirements:

(a) from 1 October 2023, all retail goods shall be marked in accordance with the requirements set out in points 2 and 3 of Annex IV, except for the following retail goods which shall bear an individual marking in accordance with point 1 of Annex IV:

(i) prepacked meat, prepacked meat products and meat packed on sales premises;

(ii) prepacked milk, prepacked dairy products and dairy products packed on sales premises listed in Part 1 of Annex V;

(b) from 1 October 2024, all milk and dairy products shall bear an individual marking in accordance with point 1 of Annex IV;

(c) from 1 July 2025, all retail goods shall bear an individual marking in accordance with the requirements set out in point 1 of Annex IV, except for the retail goods listed in Part 2 of Annex V, which shall be marked in accordance with the requirements set out in points 2 and 3 of Annex IV.

2. By way of derogation from paragraph 1:

(a) individual goods sold loose or by weight on the sales premises at the consumer's request, including individual goods processed and sold on the sales premises by a retailer for direct consumption by the consumer, shall be marked in accordance with the requirements set out in points 2 and 3 of Annex IV;

(b) individual goods offered by a catering operator, at factory canteens, by institutional catering, by restaurants and by other similar food service operators for direct consumption on the spot shall not be required to bear a marking.

3. The Commission is empowered to adopt delegated acts in accordance with Articles 16 and 17 in order to amend Annex IV by adapting the marking requirements in response to technical or operational developments.

4. The Commission shall monitor whether all retail goods are marked in accordance with paragraph 1.

Where there is evidence, such as a Union inspection report, an audit, or a notification under IMSOC or OFIS, or data on trade volumes of wine products, that retail goods do not comply with the requirements laid down in this Article or are found on the market in a Member State, the Commission may amend Annexes IV and V by means of a delegated act adopted in accordance with Articles 16 and 17.

5. The Commission is empowered to adopt delegated acts in accordance with Articles 16 and 17 to amend the list of retail goods set out in Part 2 of Annex V in accordance with the following criteria:

(a) a retail good shall be added to that list where the individual marking of that retail good is not required as official controls are no longer required at border control posts in accordance with Regulation (EU) 2017/625;

(b) a retail good shall be removed from that list where the individual marking is required for the purposes of Articles 4 and 5 of this Regulation, or where official controls are required at border controls posts in accordance with Regulation (EU) 2017/625.

6. Where the Commission assesses in accordance with Article 9(1) and (3) that the relevant public health and consumer information rules laid down in the Union acts or parts thereof listed and indicated with an asterisk in Annex I apply under the national law of the United Kingdom, it may adopt a delegated act in accordance with Article 16 to amend Annex V by adding categories of retail goods authorised to be marked in accordance with the requirements set out in points 2 and 3 of Annex IV.

Where the United Kingdom has not informed the Commission that a Union act or an amendment to a Union act applies under its national law and provided evidence thereof in accordance with Article 9(5), the Commission shall adopt a delegated act in accordance with Articles 16 and 17 to amend Annex V by removing the categories of retail goods concerned.

Article 7

Monitoring of retail goods

1. The competent authorities of the United Kingdom shall monitor the consignments of retail goods entering into Northern Ireland from other parts of the United Kingdom in accordance with the monitoring requirements set out in Part 1 of Annex III.

2. The Commission is empowered to adopt delegated acts in accordance with Articles 16 and 17 to amend Part 1 of Annex III by adapting the monitoring requirements to technical or operational developments for the purposes of monitoring the consignments of retail goods.

Article 8

Listing of establishments for the purpose of the dispatch of consignments of retail goods to Northern Ireland from other parts of the United Kingdom and their reception in Northern Ireland

1. Consignments of retail goods shall be dispatched from establishments in parts of the United Kingdom other than Northern Ireland and received by establishments in Northern Ireland listed respectively for that purpose by the competent authorities of the United Kingdom in accordance with the requirements for the listing of establishments set out in Part 2 of Annex III.

2. The Commission is empowered to adopt delegated acts in accordance with Articles 16 and 17 to amend Part 2 of Annex III by adapting the requirements for the listing of establishments to technical or operational developments for the purposes of Articles 4 and 5.

Article 9

Specific rules for consignments of rest-of-the-world retail goods

1. Rest-of-the-world retail goods which consist of commodities of animal or plant origin or composite products subject to the animal health or plant health rules referred to in Article 1(2), points (d), (e) and (g), of Regulation (EU) 2017/625 may enter into Northern Ireland from other parts of the United Kingdom and be placed on the market in Northern Ireland in accordance with Article 4 of this Regulation only in the event that:

(a) the United Kingdom decides to comply with the following requirements, and as a result provides written evidence that:

(i) the import conditions and official controls requirements provided for in Regulations (EC) No 1069/2009, (EU) 2016/429, (EU) 2016/2031 and (EU) 2017/625 and in the Commission acts adopted pursuant to those Regulations apply to those commodities under the national law of the United Kingdom; and

(ii) the import conditions and official controls requirements referred to in point (a)(i) are effectively implemented by the United Kingdom;

(b) those commodities are listed in an implementing act adopted in accordance with paragraph 4.

2. Without prejudice to paragraph 1 of this Article, fishery products caught by a vessel flying the flag of a third country other than the United Kingdom and imported into parts of the United Kingdom other than Northern Ireland may enter into Northern Ireland from other parts of the United Kingdom as retail goods, and be placed on the market in Northern Ireland in accordance with Article 4, only in the event that:

(a) the United Kingdom decides to comply with the following requirements, and as a result provides written evidence that:

(i) import conditions, official controls and verification requirements apply under the national law of the United Kingdom, thereby ensuring that fishery products obtained from illegal, unreported and unregulated fishing as defined in Article 2 of Regulation (EC) No 1005/2008 and in Union acts adopted pursuant to that Regulation are not imported into the United Kingdom;

(ii) the import conditions, official controls and verification requirements referred to in point (i) are effectively implemented by the United Kingdom;

(b) the flag State of the fishing vessel concerned is listed in an implementing act adopted in accordance with paragraph 4.

When the United Kingdom intends to introduce new measures or amend existing measures relevant to the import conditions, official controls and verification requirements referred to in point (a)(i) of this paragraph, it shall inform the Commission without delay and provide information concerning the content of such measures before the date of application of those measures in its national law.

When the Union intends to introduce new measures with regard to a flag State which have an impact on an implementing act adopted pursuant to paragraph 4 of this Article, it shall inform the United Kingdom without delay and provide information concerning the content of the new measures before the date of application of those measures.

3. To assess the effective implementation of the import conditions, official controls and verification requirements referred to in paragraphs 1 and 2, as applicable, the Commission may carry out audits and verification procedures in the United Kingdom, which may include the following:

(a) an assessment of all or part of the total control plan of the competent authorities of the United Kingdom, including, where appropriate, reviews of the inspections and audit programmes;

(b) an assessment as to whether the import conditions, official controls and verification requirements referred to in paragraphs 1 and 2 are effectively implemented as part of the national law of the United Kingdom;

(c) on-the-spot verification.

The Commission shall report on the findings of each audit performed and make the report available to Member States and to the United Kingdom.

4. Where the Commission has received the written evidence referred to in paragraphs 1 and 2, the Commission may, by means of implementing acts, adopt measures listing:

(a) the commodities of animal or plant origin or composite products and their third countries of origin that may enter into Northern Ireland as retail goods from other parts of the United Kingdom, and be placed on the market in Northern Ireland;

(b) the flag States referred to in paragraph 2, point (b).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

5. When the Commission prepares Union acts referred to in paragraph 1, point (a)(i), or amendments to such acts, it shall inform the United Kingdom and shall provide it with information relevant thereto.

The United Kingdom shall inform the Commission at the latest 15 days before the date of application of the Union acts or amendments referred to in the first subparagraph if the import conditions, official controls and verification requirements laid down in those Union acts or amendments apply as part of its national law at the date of application of those Union acts or amendments and provide evidence thereof.

In the case of Union acts or amendments that are immediately applicable, the Commission shall inform the United Kingdom as soon as possible of those acts or amendments. The United Kingdom shall inform the Commission no later than three days before the date of entry into force of those acts or amendments if the import conditions, official controls and verification requirements apply as part of its national law.

Where the United Kingdom has not informed the Commission that a Union act or an amendment thereto applies under its national law and provided evidence thereof in accordance with the second and third subparagraphs of this paragraph, the Commission shall adopt an immediately applicable implementing act in accordance with the examination procedure referred to in Article 18(2) and (3) in order to remove the commodities concerned by the Union act or the amendment thereto which does not apply under the national law of the United Kingdom from the lists established in accordance with paragraph 4 of this Article.

6. The Commission shall monitor the application by the United Kingdom of the import conditions, official controls and verification requirements referred to in paragraphs 1 and 2, as applicable.

Where there is evidence, such as a Commission assessment, a verification under paragraph 3, a Union inspection report, an audit or a notification under IMSOC, that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the import conditions referred to in paragraphs 1 and 2, or does not effectively carry out the official controls or the verification requirements referred to in those paragraphs, or that the United Kingdom does not apply one of those import conditions, official controls or verification requirements under its national law, the Commission shall adopt an immediately applicable implementing act laying down appropriate measures, which may include the removal of certain commodities or third countries of origin or certain flag States from the lists established in accordance with paragraph 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3).

CHAPTER 3

SPECIFIC RULES FOR ENTRY INTO NORTHERN IRELAND FROM OTHER PARTS OF THE UNITED KINGDOM OF CONSIGNMENTS OF PLANTS FOR PLANTING OTHER THAN SEED POTATOES, OF MACHINERY AND VEHICLES WHICH HAVE BEEN OPERATED FOR AGRICULTURAL OR FORESTRY PURPOSES AND OF SEED POTATOES FOR PLACING ON THE MARKET AND USE IN NORTHERN IRELAND

Article 10

Specific rules for consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes, for dispatch and sale by professional operators

1. The entry into Northern Ireland from other parts of the United Kingdom and the placing on the market in Northern Ireland of consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes before entering into Northern Ireland shall be subject to specific rules and a plant health label requirement only where all of the following conditions are fulfilled:

(a) those consignments are dispatched by professional operators in parts of the United Kingdom other than Northern Ireland who have been authorised and registered by the competent authorities of the United Kingdom for the purpose of guaranteeing that those consignments are dispatched in accordance with this Regulation for reception by professional operators in Northern Ireland or for immediate sale in the United Kingdom after their reception in Northern Ireland by professional operators;

(b) the smallest applicable trade units of plants for planting other than seed potatoes in each consignment and machinery and vehicles which have been operated for agricultural or forestry purposes before entry into Northern Ireland bear a plant health label issued by a professional operator, under the official supervision of the competent authorities of the United Kingdom, which complies with the content and model form laid down in an implementing act adopted in accordance with paragraph 3;

(c) the consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes before entering into Northern Ireland comply with the rules for their entry into the Union laid down in Regulations (EU) 2016/2031 and (EU) 2017/625;

(d) the consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes before entry into Northern Ireland, following their entry into Northern Ireland, are only to be placed on the market and used in the United Kingdom and are not subsequently to be moved to a Member State;

(e) the plants for planting other than seed potatoes, and machinery and vehicles which have been operated for agricultural or forestry purposes before entry into Northern Ireland are presented for official controls at SPS Inspection Facilities of first arrival in Northern Ireland in accordance with Regulation (EU) 2017/625;

(f) the professional operators in Northern Ireland that receive those plants for planting other than seed potatoes, and the professional operators that receive for the first time that machinery and those vehicles after their entry into Northern Ireland, are registered respectively for that purpose by the competent authorities of the United Kingdom in the register provided for in Article 65(1) of Regulation (EU) 2016/2031 and in accordance with the procedure laid down in Article 66 of that Regulation;

(g) written guarantees have been provided by the United Kingdom that a process of authorisation and registration of professional operators is in place to ensure that those consignments are dispatched in accordance with this Regulation, including official procedures to ensure their compliance with this Regulation and to address non-compliance, that official controls on consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes before entry into Northern Ireland at SPS Inspection Facilities of first arrival in Northern Ireland that comply with the requirements set out in Annex II to this Regulation are carried out in accordance with Regulation (EU) 2017/625, and that official controls, evidenced through a control plan, and surveillance measures are carried out covering the movements of those consignments from the SPS Inspection Facilities of first arrival in Northern Ireland to the place of destination in Northern Ireland to ensure that those consignments will not be subsequently moved to a Member State; those written guarantees thereby provide assurance to the Union that the specific rules laid down in this Article do not increase the risk to plant health on the island of Ireland, do not adversely affect the SPS status of the island of Ireland, and do not increase the risk to plant health in the internal market or affect its integrity;

(h) the Commission has adopted an implementing act in accordance with paragraph 3 of this Article concerning the content and the model form of the plant health label and has not suspended the application of the specific rules referred to in points (a), (b) and (c) of this paragraph in accordance with paragraph 4 of this Article or in accordance with Article 14.

2. The plant health label referred to in paragraph 1 shall attest that the consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes before entering into Northern Ireland comply with the requirements referred to in paragraph 1, points (a), (c) and (d).

3. Where the conditions concerning the written guarantees laid down in paragraph 1, point (g), are fulfilled, the Commission may, by means of implementing acts, lay down rules on the content and the model forms of the plant health label referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3).

4. The Commission shall monitor the application by the United Kingdom of the specific rules referred to in paragraphs 1 and 3 concerning the consignments of plants for planting other than seed potatoes, and of machinery and vehicles which have been operated for agricultural or forestry purposes, and the plant health label.

Where there is evidence, such as a Union inspection report, an audit or a notification under IMSOC, that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the conditions referred to in paragraph 1, points (a) to (g), the Commission shall, after having duly informed and consulted with the United Kingdom, adopt an implementing act laying down appropriate special conditions and measures, including temporary or permanent restrictions on the application of the specific rules relating to certain consignments or operators, or amending the implementing acts adopted in accordance with paragraph 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3).

Article 11

Specific rules for consignments of seed potatoes

1. The entry into Northern Ireland from other parts of the United Kingdom of consignments of seed potatoes for placing on the market shall be subject to specific rules and a plant health label requirement only where all of the following conditions are fulfilled:

(a) those consignments are dispatched by professional operators who have been authorised and registered by the competent authorities of the United Kingdom for the purpose of guaranteeing that those consignments are dispatched in accordance with this Regulation in other parts of the United Kingdom for reception by professional operators in Northern Ireland;

(b) each consignment of seed potatoes bears a plant health label in accordance with paragraph 2;

(c) the seed potatoes comply with requirements of the implementing act adopted in accordance with paragraph 3, concerning the entry of seed potatoes into Northern Ireland from other parts of the United Kingdom and placing on the market in Northern Ireland;

(d) the seed potatoes, following their entry into Northern Ireland, are solely intended to be placed on the market and used in the United Kingdom and are not subsequently to be moved to a Member State;

(e) the seed potatoes are presented for official controls at SPS Inspection Facilities of first arrival in Northern Ireland in accordance with Regulation (EU) 2017/625;

(f) written guarantees have been provided by the United Kingdom that a process of registration and authorisation of professional operators is in place, including official procedures to ensure compliance with this Regulation and address non-compliance, and that official controls on consignments of seed potatoes at SPS Inspection Facilities of first arrival in Northern Ireland, that comply with the requirements set out in Annex II to this Regulation, are

carried out in accordance with Regulation (EU) 2017/625, and that official controls and surveillance measures are carried out covering the movements of those consignments from the SPS Inspection Facilities of first arrival in Northern Ireland to the place of destination in Northern Ireland to ensure that those consignments will not subsequently be moved to a Member State; those written guarantees thereby provide assurance to the Union that the specific rules laid down in this Article do not increase the risk to plant health on the island of Ireland, do not adversely affect the SPS status of the island of Ireland, and do not increase the risk to plant health in the internal market or affect its integrity;

(g) the Commission has adopted an implementing act in accordance with paragraph 3 of this Article and has not suspended the application of the specific rules referred to in paragraph 1 of this Article in accordance with paragraph 4 of this Article or in accordance with Article 14.

2. The plant health label referred to in paragraph 1 shall be issued by the competent authorities of the United Kingdom, following systematic and physical official inspections, and shall be printed either by those competent authorities or by the professional operators under the official supervision of those competent authorities.

It shall attest that the consignments of seed potatoes comply with the requirements referred to in paragraph 1, points (a), (c) and (d), and the rules in an implementing act adopted in accordance with paragraph 3.

3. Where the conditions concerning the written guarantees laid down in paragraph 1, point (f), are fulfilled, the Commission may, by means of implementing acts, lay down rules on:

(a) the requirements for the entry of seed potatoes into Northern Ireland from other parts of the United Kingdom, and their use in Northern Ireland;

(b) the model form of the plant health label referred to in paragraph 1.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3).

4. The Commission shall monitor the application by the United Kingdom of the conditions referred to in paragraphs 1 and 3 concerning the consignments of seed potatoes, and the plant health label.

Where there is evidence, such as a Union inspection report, an audit or a notification under IMSOC, that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the conditions referred to in paragraph 1, points (a) to (f), the Commission shall, after having duly informed and consulted with the United Kingdom, adopt an implementing act laying down appropriate special conditions and measures, including temporary or permanent restrictions on the application of the specific rules relating to certain consignments or operators, or amending the implementing acts adopted in accordance with paragraph 3 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3).

CHAPTER 4

SPECIFIC RULES FOR THE NON-COMMERCIAL MOVEMENTS OF PET ANIMALS ENTERING INTO NORTHERN IRELAND FROM OTHER PARTS OF THE UNITED KINGDOM

Article 12

Specific rules for non-commercial movement of pet animals

1. The specific rules laid down in this Article for non-commercial movements of pet animals entering into Northern Ireland from other parts of the United Kingdom shall only apply where all of the following conditions are fulfilled:

(a) written guarantees have been provided by the United Kingdom that:

(i) those pet animals do not increase the risk to animal health on the island of Ireland or affect its sanitary status, or increase the risk to public and animal health in the internal market or undermine its integrity;

(ii) the competent authorities of the United Kingdom take effective action to reduce, to a minimum, the possibility of pet animals being moved from Northern Ireland to a Member State, evidenced through information on the official procedures for deciding which measures to take in the case of non-compliance;

(iii) the competent authorities of the United Kingdom apply requirements related to non-commercial movements of pet animals into the United Kingdom to protect its animal health status;

(iv) the competent authorities of the United Kingdom carry out effective documentary and identity checks on pet animals entering into Northern Ireland from other parts of the United Kingdom in accordance with point (f);

(v) the competent authorities of the United Kingdom implement an early detection and notification system for *Echinococcus multilocularis* infection in wild definitive host animals, and immediately notify the Commission of any such detection;

(vi) the competent authorities of the United Kingdom implement an early detection and notification system for rabies infection in kept and wild susceptible animals, and immediately notify the Commission of any suspicion or detection of rabies infection by the competent authorities of the United Kingdom;

(b) the Commission has adopted an implementing act in accordance with paragraph 4;

(c) the pet animals originate in parts of the United Kingdom other than Northern Ireland and will not be subsequently moved to a Member State;

(d) the pet animals are identified with a transponder that complies with the technical requirements set out in Annex II to Regulation (EU) No 576/2013;

(e) the pet animals are accompanied by a pet travel document, in written or electronic format, in accordance with paragraph 4, which has been validated by the competent authorities of the United Kingdom in accordance with paragraph 2, and a signed declaration is provided by the owner or authorised person that those pet animals identified in accordance with point (d) and covered by the pet travel document will not be subsequently moved from Northern Ireland to a Member State;

(f) the competent authorities of the United Kingdom carry out documentary and identity checks on the pet animals accompanied by the pet travel document and declaration as referred to in point (e), presented by the owner or authorised person after boarding has been completed and before arrival in Northern Ireland, or at the time of first arrival into Northern Ireland, to demonstrate compliance with the specific rules laid down in this Article; in the case of non-compliance revealed during those checks as provided in the official procedures referred to in point (a)(ii), the pet animals shall be presented to the competent authorities of the United Kingdom at the SPS Inspection Facilities of first arrival in Northern Ireland that comply with the requirements set out in Annex II to remedy such non-compliance.

2. The pet travel document referred to in paragraph 1, point (e), shall only be issued after the competent authorities of the United Kingdom have duly verified that the relevant entries in the document have been correctly and truthfully completed with the information required by an implementing act adopted in accordance with paragraph 4, thereby certifying compliance with the conditions laid down in paragraph 1, points (c) and (d).

3. For the non-commercial movement of pet animals originating in Northern Ireland which only travel to other parts of the United Kingdom and subsequently directly return to Northern Ireland:

(i) the pet animals shall be identified with a transponder in accordance with the requirements laid down in paragraph 1, point (d);

(ii) the requirements laid down in paragraph 1, points (c), (e) and (f), shall not apply;

(iii) the relevant requirements laid down in Regulation (EU) No 576/2013 shall not apply.

4. Where the conditions laid down in paragraph 1, point (a), are fulfilled, the Commission may, by means of implementing acts, lay down rules on the information to be included in the pet travel document for non-commercial movements of pet animals entering into Northern Ireland from other parts of the United Kingdom, including the content of the declaration referred to in paragraph 1, point (e).

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

5. The Commission shall monitor the application by the United Kingdom of the conditions referred to in paragraphs 1, 2 and 3.

Where there is evidence, such as a Union inspection report, an audit, or a notification under IMSOC that the United Kingdom does not take appropriate measures to tackle serious or repeated infringements of the conditions laid down in paragraphs 1, 2 and 3, the Commission shall, after having duly informed and consulted with the United Kingdom, adopt an implementing act laying down appropriate special conditions and measures, or amending the implementing acts adopted in accordance with paragraph 4.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2) and (3),

CHAPTER 5

PROHIBITION AND SUSPENSION

Article 13

Prohibition against the movement to, or placing on the market in, a Member State of goods and pet animals falling within the scope of this Regulation

1. Goods falling within the scope of this Regulation shall not be moved from Northern Ireland to a Member State or be placed on the market in a Member State.

2. Pet animals falling within the scope of this Regulation shall not be moved from Northern Ireland to a Member - State.

3. The Member States shall apply effective, proportionate and dissuasive penalties in the case of non-compliance with the specific rules laid down in this Regulation.

Article 14

Suspension of the specific rules laid down in Chapters 2, 3 and 4

1. The Commission shall closely monitor the application of the specific rules laid down in Chapters 2, 3 and 4 and Article 13, and in particular whether:

(a) official controls are carried out on consignments of retail goods, plants for planting other than seed potatoes, machinery and vehicles which have been operated for agricultural or forestry purposes before entry into Northern Ireland, and of seed potatoes, and on pet animals falling within the scope of this Regulation;

(b) adequate official controls and monitoring in accordance with the requirements set out in Annex III are in place covering the movements of retail goods from the SPS Inspection Facilities of first arrival in Northern Ireland to the listed establishment of destination to ensure that the retail goods are solely intended for listed establishments in Northern Ireland and will not be subsequently moved to a Member State;

(c) the specific rules laid down in this Regulation, and in particular Articles 6 and 9, are complied with.

2. The Commission shall monitor whether:

(a) the SPS Inspection Facilities of first arrival in Northern Ireland comply with Annex II;

(b) the Union representatives have ongoing and continuous access to the relevant databases used by the competent authorities of the United Kingdom in Northern Ireland for the purpose of official controls and monitoring required by this Regulation, including the Common Health Entry document (CHED) Inspection Platform and other relevant databases and exchange of information, and whether the competent authorities of the United Kingdom in Northern Ireland comply with their obligation to use Traces as provided for in Regulation (EU) 2017/625.

3. Where the Commission finds that there is a systemic failure by the United Kingdom to comply with the specific rules referred to in paragraph 1, or that the United Kingdom does not comply with one of the conditions referred to in paragraph 2, the Commission shall, within a period of seven days, notify the United Kingdom in writing of that finding and of the detailed reasons for it.

4. For a period of four weeks following the date of the written notification referred to in paragraph 3, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to the written notification.

5. If the situation giving rise to the written notification referred to in paragraph 3 of this Article is not remedied within the period of four weeks referred to in paragraph 4 of this Article or where relevant provisions of Section 2 (Determination of goods not at risk and repeal of Decision No 4/2020) of Joint Committee Decision No 1/2023 ([16]) have been suspended in accordance with Article 15(2) thereof on grounds relevant for the matters falling within the scope of this Regulation, the Commission is empowered to adopt within a further period of four weeks a delegated act in accordance with Article 17 to supplement this Regulation, by determining the specific rules laid down in this Regulation whose application shall be suspended.

If the United Kingdom fails to comply with the conditions laid down in paragraph 1, point (c), or in paragraph 2, point (a) or (b), of this Article, the Commission shall adopt a delegated act in accordance with Article 17 to supplement this Regulation by suspending the application of Articles 4, 5, 6 and 9 to 12.

6. Where the situation giving rise to the adoption of the delegated act referred to in paragraph 5 has been remedied by the United Kingdom, the Commission shall adopt a delegated act in accordance with Article 17 to supplement this Regulation by determining which of the suspended specific rules shall apply again.

CHAPTER 6

DELEGATED AND IMPLEMENTING ACTS

Article 15

Amendments to Annexes I and II

1. The Commission is empowered to adopt delegated acts in accordance with Article 16 to amend the list in Annex I to this Regulation where Union acts or parts thereof referred to in Annex 2 to the Protocol need to be removed or added.

2. The Commission is empowered to adopt delegated acts in accordance with Articles 16 and 17 to amend the requirements for SPS Inspection Facilities set out in Annex II, where necessary and appropriate to take account of relevant technical and operational developments, provided that such amendments are consistent with the specific rules laid down in this Regulation.

Article 16

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.

([16]) OJ L 102, 17.4.2023, p. 61.

2. The power to adopt delegated acts referred to in Articles 6(3) to (6), 7(2), 8(2), 14(5) and (6) and 15(1) and (2) shall be conferred on the Commission for a period of five years from 2 July 2023. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 6(3) to (6), 7(2), 8(2), 14(5) and (6) and 15(1) and (2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. 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.

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 6(3) to (6), 7(2), 8(2), 14(5) and (6) and 15(1) and (2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 17

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 16(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 18

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Plants, Animals, Food and Feed established by Article 58(1) of Regulation (EC) No 178/2002.

However, the Commission shall be assisted by the Committee for Fisheries and Aquaculture established by Article 47 of Regulation (EU) No 1380/2013 of the European Parliament and of the Council ([17]) for the purposes of Article 9(4), point (b), of this Regulation. It shall also be assisted by that Committee for the purposes of Articles 4(4) and 9(6) of this Regulation for matters falling exclusively within the scope of that Committee.

Those committees shall be committees within the meaning of Regulation (EU) No 182/2011.

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

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

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

([17]) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

CHAPTER 7

TRANSITIONAL AND FINAL PROVISIONS

Article 19

Transitional provisions for marking requirements

1. Retail goods placed on the market in Northern Ireland before 1 October 2023 shall not be required to comply with the marking requirements laid down in Article 6(1), point (a), until 31 October 2023.

2. Retail goods placed on the market in Northern Ireland before 1 October 2024 shall not be required to comply with the marking requirements laid down in Article 6(1), point (b), until 31 October 2024.

3. Retail goods placed on the market in Northern Ireland before 1 July 2025 shall not be required to comply with the marking requirements laid down in Article 6(1), point (c), until 31 July 2025.

Article 20

Entry into force

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

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

Done at Strasbourg, 14 June 2023.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	J. ROSWALL

ANNEX I

List of Union acts or parts thereof

Note: In the following list of Union acts or parts thereof referred to in Article 1(2), those relevant for public health and consumer information referred to in Article 6(6) are indicated with an asterisk '*':

1. *Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs ([1])

2. Commission Regulation (EEC) No 3703/85 of 23 December 1985 laying down detailed rules for applying the common marketing standards for certain fresh or chilled fish ([2])

3. *Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption ([3])

4. Council Regulation (EEC) No 2136/89 of 21 June 1989 laying down common marketing standards for preserved sardines and trade descriptions for preserved sardines and sardine-type products ([4])

5. Council Regulation (EEC) No 1536/92 of 9 June 1992 laying down common marketing standards for preserved tuna and bonito ([5])

6. *Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ([6])

7. *Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC ([7])

8. Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products ([8])

9. *Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation ([9])

([1]) OJ L 277, 20.10.1984, p. 12.
([2]) OJ L 351, 28.12.1985, p. 63.
([3]) OJ L 40, 11.2.1989, p. 34.
([4]) OJ L 212, 22.7.1989, p. 79.
([5]) OJ L 163, 17.6.1992, p. 1.
([6]) OJ L 37, 13.2.1993, p. 1.
([7]) OJ L 125, 23.5.1996, p. 3.
([8]) OJ L 334, 23.12.1996, p. 1.
([9]) OJ L 66, 13.3.1999, p. 16.

10. *Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation ([10])

11. *Directive 1999/4/EC of the European Parliament and of the Council of 22 February 1999 relating to coffee extracts and chicory extracts ([11])

12. *Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption ([12])

13. *Part C of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([13])

14. *Council Directive 2001/110/EC of 20 December 2001 relating to honey ([14])

15. *Council Directive 2001/111/EC of 20 December 2001 relating to certain sugars intended for human consumption ([15])

16. *Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption ([16])

17. *Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption ([17])

18. *Council Directive 2001/114/EC of 20 December 2001 relating to certain partly or wholly dehydrated preserved milk for human consumption ([18])

19. Council Regulation (EC) No 1035/2001 of 22 May 2001 establishing a catch documentation scheme for *Dissostichus* spp. ([19])

20. *Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed ([20])

([10]) OJ L 66, 13.3.1999, p. 24.
([11]) OJ L 66, 13.3.1999, p. 26.
([12]) OJ L 197, 3.8.2000, p. 19.
([13]) OJ L 106, 17.4.2001, p. 1.
([14]) OJ L 10, 12.1.2002, p. 47.
([15]) OJ L 10, 12.1.2002, p. 53.
([16]) OJ L 10, 12.1.2002, p. 58.
([17]) OJ L 10, 12.1.2002, p. 67.
([18]) OJ L 15, 17.1.2002, p. 19.
([19]) OJ L 145, 31.5.2001, p. 1.
([20]) OJ L 140, 30.5.2002, p. 10.

21. *Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ([21])

22. *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([22])

23. *Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([23]), with the exception of the second paragraph of Article 32

24. *Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ([24])

25. *Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([25])

26. *Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms ([26])

27. *Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents ([27])

28. *Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods ([28])

29. *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([29])

30. *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([30])

([21]) OJ L 183, 12.7.2002, p. 51.
([22]) OJ L 31, 1.2.2002, p. 1.
([23]) OJ L 268, 18.10.2003, p. 1.
([24]) OJ L 268, 18.10.2003, p. 24.
([25]) OJ L 268, 18.10.2003, p. 29.
([26]) OJ L 287, 5.11.2003, p. 1.
([27]) OJ L 325, 12.12.2003, p. 1.
([28]) OJ L 309, 26.11.2003, p. 1.
([29]) OJ L 139, 30.4.2004, p. 1.
([30]) OJ L 139, 30.4.2004, p. 55.

31. *Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ([31])

32. *Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene ([32])

33. *Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ([33])

34. *Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([34])

35. *Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ([35])

36. Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC ([36])

37. Council Regulation (EC) No 1100/2007 of 18 September 2007 establishing measures for the recovery of the stock of European eel ([37]), insofar as it concerns provisions relating to marketing standards

38. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 ([38])

39. 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 ([39])

40. *Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([40])

41. *Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 ([41])

([31]) OJ L 338, 13.11.2004, p. 4.
([32]) OJ L 35, 8.2.2005, p. 1.
([33]) OJ L 70, 16.3.2005, p. 1.
([34]) OJ L 404, 30.12.2006, p. 9.
([35]) OJ L 404, 30.12.2006, p. 26.
([36]) OJ L 247, 21.9.2007 p. 17.
([37]) OJ L 248, 22.9.2007, p. 17.
([38]) OJ L 218, 13.8.2008, p. 30.
([39]) OJ L 218, 13.8.2008, p. 82.
([40]) OJ L 354, 31.12.2008, p. 1.
([41]) OJ L 354, 31.12.2008, p. 7.

42. *Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ([42])

43. *Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ([43])

44. *Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients ([44])

45. *Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters ([45])

46. *Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([46])

47. *Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC ([47])

48. *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 ([48])

49. Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 ([49]), insofar as it concerns provisions relating to marketing standards

50. Regulation (EU) No 640/2010 of the European Parliament and of the Council of 7 July 2010 establishing a catch documentation programme for bluefin tuna *Thunnus thynnus* and amending Council Regulation (EC) No 1984/2003 ([50])

([42]) OJ L 354, 31.12.2008, p. 16.
([43]) OJ L 354, 31.12.2008, p. 34.
([44]) OJ L 141, 6.6.2009, p. 3.
([45]) OJ L 164, 26.6.2009, p. 45.
([46]) OJ L 152, 16.6.2009, p. 11.
([47]) OJ L 229, 1.9.2009, p. 1.
([48]) OJ L 309, 24.11.2009, p. 1.
([49]) OJ L 343, 22.12.2009, p. 1.
([50]) OJ L 194, 24.7.2010, p. 1.

51. *Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([51])

52. *Regulation (EU) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 ([52])

53. *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([53])

54. Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 ([54])

55. *Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 ([55])

56. *Sections 1 and 3 of Chapter I of Title II of Part II of Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([56])

57. Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC ([57]), insofar as it concerns provisions relating to marketing standards for fishery and aquaculture products

58. *Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling of aromatised wine products and repealing Council Regulation (EEC) No 1601/91 ([58])

59. *Directive (EU) 2015/2203 of the European Parliament and of the Council of 25 November 2015 on the approximation of the laws of the Member States relating to caseins and caseinates intended for human consumption and repealing Council Directive 83/417/EEC ([59])

([51]) OJ L 157, 15.6.2011, p. 1.
([52]) OJ L 304, 22.11.2011, p. 18.
([53]) OJ L 167, 27.6.2012, p. 1.
([54]) OJ L 181, 29.6.2013, p. 15.
([55]) OJ L 181, 29.6.2013, p. 35.
([56]) OJ L 347, 20.12.2013, p. 671.
([57]) OJ L 354, 28.12.2013, p. 22.
([58]) OJ L 84, 20.3.2014, p. 14.
([59]) OJ L 314, 1.12.2015, p. 1.

60. *Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([60])

61. *Council Regulation (Euratom) 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90 ([61])

62. *Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 ([62])

63. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC ([63])

64. *Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ([64])

65. *Chapter II of Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 ([65]) and Chapter 1 thereof insofar as it prohibits the use of synthetic alcohol and certain colourings

66. Regulation (EU) 2019/1241 of the European Parliament and of the Council of 20 June 2019 on the conservation of fisheries resources and the protection of marine ecosystems through technical measures, amending Council Regulations (EC) No 1967/2006, (EC) No 1224/2009 and Regulations (EU) No 1380/2013, (EU) 2016/1139, (EU) 2018/973, (EU) 2019/472 and (EU) 2019/1022 of the European Parliament and of the Council, and repealing Council Regulations (EC) No 894/97, (EC) No 850/98, (EC) No 2549/2000, (EC) No 254/2002, (EC) No 812/2004 and (EC) No 2187/2005 ([66]), insofar as it concerns provisions relating to minimum sizes of marine organisms that also constitute minimum marketing sizes

67. *Commission Delegated Regulation (EU) 2022/2292 of 6 September 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption ([67])

([60]) OJ L 327, 11.12.2015, p. 1.
([61]) OJ L 13, 20.1.2016, p. 2.
([62]) OJ L 150, 14.6.2018, p. 1.
([63]) OJ L 4, 7.1.2019, p. 1.
([64]) OJ L 4, 7.1.2019, p. 43.
([65]) OJ L 130, 17.5.2019, p. 1.
([66]) OJ L 198, 25.7.2019, p. 105.
([67]) OJ L 304, 24.11.2022, p. 1.

ANNEX II

Requirements for SPS Inspection Facilities

The structural and human resources of the SPS Inspection Facilities in Northern Ireland shall have the capacity and the capability adapted to the type and volume of the retail goods presented for the official controls required by this Regulation.

They shall also have the capacity and capability adapted to the type and volume of animals and goods not falling within the scope of this Regulation presented for the official controls required by Regulation (EU) 2017/625.

PART 1

Operation of temporary SPS Inspection Facilities

Minimum requirements for SPS Inspection Facilities	Timeline
Sufficient number of suitably qualified staff in accordance with Article 64(3), point (a), of Regulation (EU) 2017/625.	By 1 October 2023
Adequate infrastructure to allow the performance of official controls, in accordance with Article 3(1) to (6), (11), (12) and (13), of Commission Implementing Regulation (EU) 2019/1014 ([1]).	
Adequate equipment to allow the performance of official controls in accordance with Article 4(1), points (c) and (d), and Article 4(2) and (3) of Implementing Regulation (EU) 2019/1014.	
Technology and equipment necessary for the efficient operation of Traces, and, as appropriate, of other computerised information management system necessary for the handling and exchange of data and information in accordance with Article 64(3), point (f), of Regulation (EU) 2017/625.	
Official controls, including identity and physical checks, are performed.	
SPS Inspection Facilities are operational for official controls on pet animals in accordance with Article 34 of Regulation (EU) No 576/2013, and for non-compliant pets as provided for in Article 12(1), point (f), of this Regulation.	

([1]) Commission Implementing Regulation (EU) 2019/1014 of 12 June 2019 to lay down detailed rules on minimum requirements for border control posts, including inspection centres, and for the format, categories and abbreviations to use for listing border control posts and control points (OJ L 165, 21.6.2019, p. 10).

PART 2

Construction of final SPS Inspection Facilities

Minimum requirements for SPS Inspection Facilities	Timeline
Compliance with the requirements laid down in Article 64 of Regulation (EU) 2017/625.	By 1 July 2025
Official controls, including identity and physical checks, are performed at SPS Inspection Facilities, in accordance with -Regulation (EU) 2017/625.	

The United Kingdom shall submit to the Commission a progress report as regards the completion of the SPS Inspection Facilities by 31 July 2024 and thereafter every three months until the requirements of this Annex have been satisfied.

The United Kingdom and the Commission shall cooperate on electronic certification.

ANNEX III

The requirements for monitoring and for listing of establishments referred to in Articles 7 and 8

PART 1

Monitoring requirements

1. Consignments of retail goods entering into Northern Ireland from other parts of the United Kingdom shall be monitored by the competent authorities of Northern Ireland from the SPS Inspection Facilities of first arrival in Northern Ireland to the establishment of destination in accordance with Article 2(1), Article 2(2), points (b) and (c), Article 2(3) and Article 3(2) to (5), of Commission Delegated Regulation (EU) 2019/1666 ([1]).

2. Consignments of retail goods shall be sealed by the competent authorities of the United Kingdom, or under their responsibility, and the competent authorities shall ensure that the consignments are intact and have not been tampered with between the SPS Inspection Facility of first arrival in Northern Ireland and the establishment of destination.

   The seal number of such consignments shall be issued by the competent authorities of the United Kingdom and inserted in the general certificate referred to in Article 4(1) and in Article 5(1), point (g), of this Regulation and in the Common Health Entry Document (CHED) referred to in Article 56 of Regulation (EU) 2017/625.

   The seal number shall be confirmed or reconciled by the competent authorities of Northern Ireland at the SPS Inspection Facility of first arrival in Northern Ireland. Where a consignment is resealed, the new seal number shall be recorded in the CHED.

3. The operator responsible for the establishment at the place of destination shall, within a period of two days from the date of arrival of the consignments of retail goods in Northern Ireland, inform the competent authorities of Northern Ireland responsible for performing the official controls at that establishment of the arrival of those consignments.

PART 2

Lists of establishments dispatching consignments of retail goods in parts of the United Kingdom other than Northern Ireland and lists of establishments in Northern Ireland receiving those consignments

1. The lists of establishments in parts of the United Kingdom other than Northern Ireland and in Northern Ireland authorised to dispatch or receive the delivery of consignments of retail goods shall be drawn up and kept up-to-date by the competent authorities of the United Kingdom, in accordance with publicly available procedures which shall also be kept up-to-date.

2. The competent authorities of the United Kingdom shall ensure that the establishments of dispatch and reception referred to in point 1 comply with the requirements laid down in this Regulation by carrying out risk-based and intelligence-led spot checks on those establishments. The purpose of those spot checks shall be to ensure that the retail goods are intended solely for retail sale in Northern Ireland, and that those goods will not be subsequently moved to a Member State.

([1]) Commission Delegated Regulation (EU) 2019/1666 of 24 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of destination in the Union (OJ L 255, 4.10.2019, p. 1).

3. The risk-based and intelligence-led spot checks referred to in point 2 shall ascertain, *inter alia*, compliance by the establishments with the requirements set out in Annex IV, and in particular they shall verify whether the retail goods comply with the marking requirements laid down in Article 6(1), taking into account the compliance history of those establishments and the volume of retail goods that do not bear an individual marking in accordance with Article 6(1), points (a) and (b).

   Those spot checks shall include a visual inspection of retail goods marked at box level in accordance with point 2 of Annex IV and the retail goods presented on the shelves in the establishment, as well as a review of the relevant documentation relating to the general certificate accompanying these retail goods and entry records of the establishments of destination.

   Every three months, until 30 June 2025, the United Kingdom shall submit a report to the Commission on the level and outcomes of the spot checks undertaken in accordance with point 2.

4. Where the competent authorities of the United Kingdom have reason to suspect serious or repeated infringements of the requirements laid down in this Regulation, they shall remove the establishments immediately from the lists of establishments referred to in point 1.

5. The lists of establishments referred to in point 1 shall be made available without delay electronically to the Commission and to the competent authorities in Northern Ireland.

ANNEX IV

Marking requirements

1. Individual markings

The marking shall be attached to the packaging in a conspicuous place in such a way as to be easily visible, clearly legible and indelible. It shall not be in any way hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

The marking shall state the following words: 'Not for EU'

2. Box level markings

The smallest container of the same prepacked retail goods shall bear the marking.

The marking shall be attached to the container in a conspicuous place in such a way as to be easily visible, clearly legible and indelible. It shall not be in any way hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

The marking shall state the following words: 'Not for EU'

3. Shelf-level signs and posters

A sign containing the words 'Not for EU' shall be placed next to the price tag or equivalent on the shelves in the establishment where the retail goods are presented to the final consumer.

A sufficient number of posters shall be visibly displayed in the vicinity of the retail goods informing the consumers that those retail goods are only intended for sale to the final consumers in Northern Ireland and are not to be subsequently moved to a Member State.

ANNEX V

Lists of retail goods as referred to in Article 6(1)

PART 1

Prepacked milk and dairy products required to be marked in accordance with Article 6(1), point (a)(ii):

(1) pasteurised milk;

(2) pasteurised cream;

(3) sour cream;

(4) crème fraiche;

(5) pasteurised buttermilk;

(6) unpasteurised (raw) cheese;

(7) quark/cottage cheese.

PART 2

Certain retail goods not required to be individually marked in accordance with Article 6(1), point (c)

1. The following retail goods, where they are shelf-stable composite products which comply with the requirements laid down in Article 3(1) of Commission Delegated Regulation (EU) 2021/630 [1]:

   (a) confectionery (including sweets), chocolate and other food preparations containing cocoa;

   (b) pasta, noodles and couscous, not mixed or filled with meat product;

   (c) bread, cakes, biscuits, waffles and wafers, rusks, toasted bread and similar toasted products;

   (d) olives stuffed with fish;

   (e) extracts, essences and concentrates, of coffee, tea or maté and preparations with a basis of these products or with a basis of coffee, tea or maté; roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof;

   (f) soup stocks and flavourings packaged for the final consumer;

   (g) food supplement packaged for the final consumer, containing small amounts of animal products and those including glucosamine, chondroitin or chitosan;

   (h) liqueurs and cordials.

[1] Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 17).

2. Retail goods, other than those subject to official controls at border control posts, in accordance with Article 44 of Regulation (EU) 2017/625, such as canned fruit and vegetables, flour, spices, flavourings, vinegar, seeds, nuts, popcorn, crackers, crisps, tomato ketchup, tomato soup, dried herbs, frozen chips, tea bags, dried tea leaves, and coffee.

3. The following retail goods of plant origin, except where a phytosanitary certificate is required under Union rules:

   (a) pineapples;

   (b) coconuts;

   (c) durian;

   (d) bananas;

   (e) dates.

4. Retail goods falling within the scope of Regulation (EU) No 1308/2013, unless subject to official controls at border control posts in accordance with Regulation (EU) 2017/625, such as the following:

   (a) cereals;

   (b) rice;

   (c) sugar;

   (d) olive oil and table olives;

   (e) processed fruit and vegetable products;

   (f) wine;

   (g) jam;

   (h) peanut butter;

   (i) frozen peas;

   (j) maple syrup.

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