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Taylor Wessing Redline Version

Proposal for a regulation on machinery products of the European Parliamant and of the Council

– August 2022 –

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Amendments made in Redline are intended to show the opinion of the Committee on the Internal Market and Consumer Protection of the European Parliament.

Amendments made in Redline and marked gray are intended to show the opinion of the Committee on Employment and Social Affairs of the European Parliament. If grey amendments are in brackets [EXAMPLE], they contradict or are redundant to amendments made by the Committee on the Internal Market and Consumer Protection. Amendments highlighted marked gray are intended to illustrate the legislative procedure; the Committee on the Internal Market and Consumer Protection has reached its opinion also on the basis of these changes.

The opinion of the cited Committee's can be found here: https://www.europarl.europa.eu/doceo/document/A-9-2022-0141_EN.html#_section2

The official EU document building the base of this document can be found here: https://eur-lex.europa.eu/resource.html?uri=cellar:1f0f10ee-a364-11eb-9585-01aa75ed71a1.0001.01/DOC_1&format=DOC

EUROPEAN
COMMISSION

Brussels, 21.4.2021
COM(2021) 202 final

2021/0105 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on machinery products

(Text with EEA relevance)

{SEC(2021) 165 final} - {SWD(2021) 82 final} - {SWD(2021) 83 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Reasons for and objectives of the proposal

The Machinery Directive (hereafter 'MD')[1] establishes a regulatory framework for placing machinery on the Single Market, based on Article 114 of the TFEU (the approximation of laws. The general objectives of the MD are to: i) ensure free movement of machinery within the internal market; and ii) ensure a high level of protection for users and other exposed persons. The MD follows the 'new approach' principles of EU legislation. It is intentionally written to be technology neutral, which means that it lays down the essential health and safety requirements (hereafter 'safety requirements') to be complied with, without prescribing any specific technical solution to comply with those requirements. The choice of the technical solution is a prerogative of manufacturers, which leaves space for innovation and new design development.

During the REFIT evaluation[2] of the directive, all interested parties confirmed it is an essential piece of legislation although it identified a necessity to improve, simplify and adapt the MD to the needs of the market. Some Members of the European Parliament's expressed their support to the revision of the Machinery Directive. In particular, by 'taking the legislation' to the XXI century and promoting innovation for the EU economy.

As part of the Commission Work Programme 2020 under the priority 'A Europe fit for the Digital Age', the revision of the product safety Directive 2006/42/EC on Machinery (MD)[3] contributes to the digital transition and to the strengthening of the Single Market. Indeed, regarding new technologies and their impact on safety legislation, the Commission has published in February 2020 a White Paper on Artificial Intelligence accompanied by a 'Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics'[4]. The Report, which has conducted an analysis of the impact of new technologies and the challenges they pose to Union safety legislation, concluded that the current product safety legislation contains a number of gaps that need to be addressed, in particular, among other, in the Machinery Directive. This is even more relevant for a sustainable recovery from the COVID pandemic, since the machinery sector is an essential part of the engineering industry and one of the industrial mainstays of the EU economy.

In view of dealing with the elements highlighted in the evaluation and developed in the impact assessment report of the machinery directive[5], as well as responding to the Commission policy objectives on digitalization, this proposal expects to tackle the following problems:

Problem 1: The MD does not sufficiently cover new risks originating from emerging technologies.

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1 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.
2 SWD (2018) 160 final, Evaluation of the Machinery Directive.
3 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.
4 Available at: https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics-0_en
5 SWD (2021) […] final, Impact assessment of the Machinery Directive.

In order to boost the trust in digital technologies, the MD needs to provide legal certainty as regards those technologies, existing gaps could hinder a level playing field for manufacturers, which would impact the efficiency of the MD.

There are several aspects that need to be addressed within this problem. The first one relates to the potential risks that originate from a direct human-robot collaboration as the collaborative robots (co-bots) that are designed to work alongside human and employees are exponentially increasing. A second source of potential risk originates from connected machinery. A third area of concern lies with the way software updates affects the 'behaviour' of the machinery after its placing on the market. A fourth concern relates to the ability of manufacturers to conduct a full risk assessment on machine learning applications before the product is placed on the market. Finally, as far as the autonomous machines and remote supervisory stations, the current MD foresees a driver or an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be accompanying the machinery, or may guide the machinery by remote control, but does not consider the possibility of no driver, and sets up no requirements for autonomous machines.

Problem 2: (i) Legal uncertainty due to a lack of clarity on the scope and definitions; and (ii) possible safety gaps in traditional technologies.

The MD needs greater legal certainty in its scope and definitions, which generated some difficulties for manufacturers to understand the correct legal framework they should apply. Some overlaps or inconsistencies with other EU specific legislation were identified. With respect to the definitions set by the Directive, the definition of 'partly completed machinery' raised a number of concerns particularly centred at the borderline with the definition of 'machinery' and the definition of 'machinery' has been clarified. Besides, there is a need to clarify the exclusion of means of transport and to reinforce the coherence of the exclusion of some products covered by the **Low Voltage Directive** 2014/35/EU[6] when those products integrate a Wi-Fi function.

Furthermore, it is a common practice that machines placed on the market are modified in order for example to add a function or improve the performance. The problem is that if the machine suffers a **substantial modification,** without the manufacturer's agreement, may be not in conformity any longer with the essential health and safety requirements. The current MD does not address this situation.

There are a number of requirements on **traditional technologies** not related to new technologies that were identified either as not clear or safe enough, or as too prescriptive and potentially hindering innovation. These requirements are related to installation of lifting appliances, slow speed lifts, seating, protection against hazardous substances, overhead power lines and vibration from portable handheld and hand guided machinery.

Problem 3: Insufficient provisions for high risk machines.

The third party conformity assessment is considered by some Member States and stakeholders more adapted to address the high risks stemming from certain groups of machines.

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6 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, available at: http://data.europa.eu/eli/dir/2014/35/oj.

Another problem is that **the current list of high-risk machines in Annex I was elaborated 15 years ago**, and the market has much evolved since then. It is necessary to remove machines no longer considered high risk and/or introducing new ones (such as machinery embedding AI systems, which fulfil a safety function).

Problem 4: Monetary and environmental costs due to extensive paper-based documentation.

The MD requires manufacturers to provide the necessary machinery information, such as instructions. To ensure that every machine user has access to the instructions, providing a printed version was considered as the most viable option. Since then, however, the use of the internet and digital technologies has increased. The requirement to provide printed versions increases the costs and administrative burdens for economic operators and has a negative impact on the environment. However, it must be also considered that some users are less digitally savvy, there is a lack of internet access in certain environments and the digital manual might not match the version of the product.

Problem 5: Inconsistencies with other pieces of Union product safety legislation.

The New Legislative Framework is a package of measures aimed at brought together all the elements required for a comprehensive regulatory framework to operate effectively for the safety and compliance of industrial products with the requirements adopted to protect the various public interests and for the proper functioning of the single market. A main objective of the Commission is to bring product harmonisation legislation in line with the reference provisions of Decision 768/2008/EC. While the Machinery Directive is already a New Approach directive, it is not yet aligned to the NLF.

The lack of MD's alignment to the NLF creates inconsistencies with other EU product legislation.

Problem 6: Divergences in interpretation due to transposition.

The fact that the current machinery legislation is a Directive leaving Member States to choose the means to comply with the legislative objectives, has led to different interpretations of the MD provisions creating legal uncertainty and lack of coherence throughout the single market. Furthermore, there have been delays in the transposition of the Directive in some Member States.

1.2. Consistency with existing policy provisions in the policy area

This initiative is in line with the Single Market Act[7], which stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance. With this purpose, the regulation on machinery products is aligned to the provisions of Decision No 768/2008/EC[8].

Furthemore it reinforces the coherence with the low voltage directive 2014/35/EU[9] by considering the fact that electrical and electronic products excluded from this Regulation will

7 Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions (COM(2011) 206 final).

8 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, 13.08.2008, p. 82).

9 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. 35).

be also excluded from the radio equipment directive 2014/53/EU[10] when they incorporate wi-fi.

1.3. Consistency with other Union policies

This proposal is coherent with the Union policy on artificial intelligence (AI) and the upcoming Regulation on artificial intelligence, which will address the risks having an impact on safety for high-risk AI systems embedded in a machinery or that are safety components under the future regulation on machinery products.

In addition, this proposal is coherent with the Union policy on cybersecurity, making the link with the future cybersecurity schemes pursuant to Regulation (EU) 2019/881 for the purpose of demonstrating compliance with the future regulation on machinery products.

Furthermore it contributes to simplification of the regulatory environment.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1. Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union because the purpose of the Regulation is to harmonise health and safety requirements for machinery in all Member States and to remove obstacles to trade in machinery between Member States.

2.2. Subsidiarity (for non-exclusive competence)

The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 2006/42/EC and the coherence with the AI Union policy. Without a Union wide regulation, Member States could impose diverging safety requirements, which would lead to differences in the safety of the products for the users for manufacturers when trading machinery across different countries. For instance, some market surveillance authorities consulted found necessary to ensure that software updates not foreseen in the initial manufacturer's risks assessment and having an impact on safety would require the machine to go through a conformity assessment procedure leading to a new CE marking. Furthermore, the future regulation on machinery products sets up Union wide requirements underpinned by the solutions provided in European standards. Given the Union broad level of the standardisations activities, any changes to the scope or requirements of the future regulation on machinery products must be made at Union level to avoid distorting the market, creating barriers to the free movement of products and undermining the protection of human health and well-being. In addition, the newly added provisions will align the economic operators' obligations, the traceability provisions, the provisions on the assessment and notification of conformity assessment bodies and on market surveillance.

As for the added value of action at Union level, regulatory action at the Union level, contributes to the development of the Internal (and Digital) Single Market, provides legal certainty and a level playing field for the industry, and establishes a high level of trust among machinery users.

[10] 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).

2.3. Proportionality

The preferred policy option is option 3 - Burden minimisation and enhanced safety.

This policy option addresses all identified problems in the most effective and efficient way, proposing a revised MD that is not only fit for purpose now, but also in the years to come, and ensures coherence with existing product safety legislation and with the future AI framework.

Policy option 3 adds new requirements and clarifies existing ones, in a targeted and proportional way, only when necessary and often applicable to certain types of machinery. Legal clarity is added to the current act in its scope, definitions and requirements, including those covering risk stemming from new technologies and drive the standardisation activities in this area, which enhances safety and ensures a higher level of trust and industry competitiveness in the (digital) market. It also adapts the machines presenting high risks to the state of the art, removes the internal check option for the conformity assessment of the high-risk machines, and ensures full coherence with the AI Regulation proposal. It proposes a burden reduction measure highly requested by the industry which is allowing digital documentation, while at the same time ensuring that end users and consumers can have a printed version free of charge if they so request. Finally, the revised MD will gain in coherence and legal certainty by aligning to the NLF and becoming a Regulation. To ensure proportionality, this policy option includes the standardisation process with a new Standardisation Request issued by the Commission for detailed technical solutions to be developed by the standardisation bodies, and the Machinery Guide for detailed clarification and examples.

As explained in the Impact Assessment, the preferred policy option adheres to the principle of proportionality. The proposed changes to the safety requirements are targeted, limited to certain machinery types: machinery including new technologies, specific machinery, and high-risk machinery. The burden reduction measures are on the contrary aimed at all machinery types (such as clarification of substantial modification, digital documentation, alignment to the NLF, conversion to a regulation). Proportionality is also ensured by the MD being technologically neutral. The proposed clarifications or additions to the safety requirements are kept to the strict minimum in the proposal, to be complemented by a new Standardisation Request issued by the Commission to empower the standardisation bodies to develop voluntary technical solutions.

2.4. Choice of the instrument

The proposal takes the form of a Regulation. The proposed change from a Directive to a Regulation takes into account the Commission's general objective to simplify the regulatory environment and the need to ensure a uniform implementation throughout the Union of the proposed legislation.

In addition, the machinery directive is a total harmonisation directive, which means that it establishes a high level of safety, and does not allow the Member States to impose more restrictive obligations. In this respect, a Regulation by its legal nature, would better ensure that Member States do not impose national technical requirements that go beyond the safety requirements laid down in Annex I of the current Directive and/or contradict those safety requirements.

The change from a Directive to a Regulation will not lead to any change in the regulatory approach. The characteristics of the New Approach will be fully preserved, in particular the flexibility given to manufacturers in the choice of the means employed to comply with the

essential requirements (harmonised standards or other technical specifications) and in the choice of the procedure used to demonstrate compliance from among the available conformity assessment procedures. The existing mechanisms supporting the implementation of the legislation (standardisation process, working groups, market surveillance, Member States administrative cooperation (AdCo), and the development of guidance documents…) will not be affected by the nature of the legal instrument and will continue to operate in the same manner under the Regulation as they currently do under the Directive.

Finally, the use of Regulations in the area of internal market legislation, in accordance also with the preference expressed by stakeholders, avoids the risk of 'gold plating'. It also allows manufacturers to work directly with the Regulation text instead of needing to identify and examine 27 transposition laws. On this basis, it is considered that the choice of a Regulation is the most appropriate solution for all involved parties as it will allow a more rapid and coherent application of the proposed legislation and will establish a clearer regulatory environment for economic operators.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

3.1. Ex-post evaluations/fitness checks of existing legislation

The evaluation of the directive concluded that a revision should aim to: i) address the risks stemming from new technologies while allowing for technical progress; ii) improve the legal clarity of some major concepts and definitions in the current text of the MD; iii) simplify the requirements for documentation by allowing digital formats, hence reducing administrative burden for economic operators, with an additional positive impact on environmental costs; iv) ensure coherence with other Directives and Regulations for products and improve enforcement of the legislation through the alignment to the New Legislative Framework, v) reduce costs of transposition by converting the Directive into a Regulation.

The results of the evaluation have been taken on board in the proposal.

3.2. Stakeholder consultations

Stakeholders have been consulted throughout the preparation of the revision of the MD, including Member States, manufacturers' federations, consumers and workers associations, notified bodies and representatives from standardisation organisations.

The consultation included meetings for a selected group of experts as well as consultation of the machinery Working Group and the machinery AdCo Group of market surveillance authorities.

Some stakeholder's views have evolved following discussions in the machinery Working Group and bilateral meetings, in particular on the need to address explicitly the new risks stemming from digital emerging technologies.

- **Specific objective 1: Cover new risks related to digital emerging technologies**

While most stakeholders consider that the MD takes innovations sufficiently into account, some expressed concerns over the potential impacts of emerging digital technologies on safety.

- **Specific objective 2: Ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies**

On the scope and definitions most stakeholders agreed on adapting the current exclusion of low voltage products covered by the Low-Voltage Directive (LVD) in Art. 1.2(k) of the MD to the products integrating Wi-Fi and clarifying the definition of partly completed machinery. As for introducing conformity assessment obligations linked to the substantial modification of a machinery placed on the market or put into service, the stakeholders' views diverge. Regarding the adaptation of the essential health and safety requirements for traditional machinery, most of stakeholders agree to a greater or lesser extent, except for some specific cases in which they consider that an adaptation is not necessary because other Union legislation already covers the risks.

- **Specific objective 3: Reassess machines considered as high risk and reassess related conformity procedures**

The question to whether the manufacturer internal checks option in Annex I of the MD leads to safety concerns received mixed responses in the public consultation. The interview responses, on the other hand often referred to an adaptation and regular updates of the Annex I as potential to bring benefits.

- **Specific objective 4: Reduce paper-based requirements for documentation**

On allowing digital formats for documentation, almost all the stakeholder groups representing the industry indicated that are in favour. Most Member States and consumers organisations are in favour of ensuring also paper format.

- **Specific objective 5: Ensure coherence with other product safety legislation**

Alignment to the New Legislative Framework received nearly universal support.

- **Specific objective 6: Avoid divergences in interpretation derived from transposition**

Most stakeholders wish to reduce the possible divergences in the interpretation of the machinery directive derived from transposition and mention potential benefits of converting the Directive into a Regulation. For manufacturers, a conversion could lead to a decrease of additional costs related to differences in interpretation across Member States.

3.3. Collection and use of expertise - Impact assessment

The Commission carried out an impact assessment on the revision of the machinery Directive. The Regulatory Scrutiny Board (RSB) issued an opinion on the draft impact assessment on 5 February 2021. The opinion of the Board as well as the final Impact Assessment and its executive summary are published together with this proposal.

Based on the information collected, the impact assessment examined and compared four options to address problems and issues relating to the Machinery Directive.

Option 0 Baseline - 'no change'

This option would leave the standardisation process evolve as usual, without particular focus risks stemming from new technologies, and with no particular focus on areas for improvement related to traditional technologies. It would also revise the 'Guide to application of the MD' following the normal process, with limited ambition and no particular push for consensus.

Option 1 Self-regulation by industry and changes to the Guide

This option would make no changes to the current act. Clarifications would be introduced in the 'Guide to application of the MD' with a push for consensus to clarify where possible the

main problems as described in section 1.1. New risks stemming from new technologies (as well certain risks from traditional technologies) would be addressed through the issuance of a new commission standardisation request to drive the normal standardisation process.

Option 2 Burden minimisation

The rationale behind this option is to reduce economic operators' burden. In view of achieving this objective this option aims to increase the legal clarity of some provisions and simplify some administrative obligations.

However, to minimise the economic operators' burden there would be no adaptations in the safety requirements for products, thus with no changes in the manufacturers' obligations for designing and manufacturing the machinery. The new risks stemming from new technologies (as well certain risks from traditional technologies) would be addressed through the issuance of a dedicated commission standardisation request to drive the normal standardisation process as much as possible.

Option 3 Burden minimisation and enhanced safety

This option aims also to increase the legal clarity of some provisions and simplify some administrative obligations. In addition, it seeks enhancing safety by adapting the safety requirements and tailoring the conformity assessment to the risk related to the machinery product, including new technologies.

Option 3 was found to be the preferred option because:

Option 0 means no action and would not address the problems and issues identified, with the risk of not addressing the problems and objectives.

Option 1 achieves limited results. It does not ensure an effective response to the problems.

Option 2 boosts competitiveness by minimising burden for manufacturers, without diminishing the number of unsafe products in the market.

On the contrary, option 3 boosts competitiveness by minimising burden for manufacturers, and additionally enhances safety by clarifying or adding requirements. This comes with additional costs for compliance, but also benefits related to less unsafe products in the market. This is also the most future-proof option because addresses the risks from new technologies.

3.4. Regulatory fitness and simplification

The alignment to the NLF means a better functioning of the directive and its enforcement, but also a burden simplification for manufacturers dealing with several product safety acts applying to their products (e.g. machinery to which both the machinery directive and the radio equipment directive apply). It streamlines the process of safeguard procedures, by involving manufacturers and Member States before the Commission is notified and triggers a Commission decision only in cases where there is disagreement between Member States.

Another simplification aspect is the complementarity between the AI and machinery legal proposals, where the AI regulation delegates the conformity assessment to the machinery, so that the risk assessment for the whole machinery with AI systems is done only through the future regulation on machinery products.

Finally, the change from a directive to a regulation, will avoid Member States transpositions and will ensure coherence in the interpretation of the legal act and in its implementation.

4. BUDGETARY IMPLICATIONS

This proposal does not have any implications for the Union budget.

5. OTHER ELEMENTS

5.1. Implementation plans and monitoring, evaluation and reporting arrangements

The Commission will monitor the implementation, the application and the compliance to these new provisions with a view to assessing their effectiveness. The regulation will request a regular Commission's evaluation and review and the submission of a public report in this respect to the European Parliament and to the Council.

5.2. Detailed explanation of the specific provisions of the proposal

Scope and definitions

The scope of the proposed Regulation remains the same but is clarified by adding the subject matter in Article 1, adapting the wording of the scope and adding a new indent in the definition of machinery that includes assembly missing only the upload of a software intended for its specific application to prevent manufacturers classifying them as partially completed machinery. Furthermore, the definition of safety component has been also clarified to include non-physical components such as software.

There is a new definition of substantial modification to ensure that machinery, placed on the market and/or put into service, that suffers substantial modifications is in conformity with the essential health and safety requirements in Annex III.

Additionally, the general definitions of the NLF Decision 768/2008/EC have been inserted.

The Regulation clarifies also the application of other specific Union harmonisation legislation when the risks to be addressed in the machinery are not contemplated in Annex III.

Exclusions

The exemption of the means of transport on road is extended beyond the Union type approval legislation to increase the legal certainty. The reason is to prevent that vehicles not covered by that legislation are covered by default by the machinery legislation, as this legislation is not meant to regulate risks other than those stemming from the machinery function (such as sawing, excavating, etc.), and not the risks exclusively related to its transport function of persons or goods. Furthermore, as for the exemption on the list of electrical and electronic products regulated by the Low Voltage Directive as some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council [11]as radio equipment, those products should also be excluded from the scope of this Regulation.

High-risk machinery

The proposal sets up classification rules for high-risk machinery empowering the Commission to adopt delegated acts to adapt the list of high-risk machinery in Annex I. This list is obsolete

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

and needs to be adapted to the technical progress and new type of machinery presenting high risks such as machinery with AI ensuring safety functions.

Obligations of economic operators

The proposal incorporates obligations for manufacturers, importers and distributors to be aligned with the NLF Decision 768/2008/EC. This will clarify the respective obligations, which are proportionate to the economic operators' responsibilities. Furthermore, when a machinery is substantially modified according to the definition, the one that modifies the machinery becomes manufacturer and must comply with the relevant obligations. As the complexity of the machinery supply chain is increasing, there is a general obligation of cooperation of third parties involved in the machinery supply chain, other than the economic operators.

Presumption of conformity of machinery

The presumption of conformity of machinery when manufacturers apply the relevant harmonised standards or parts thereof published in the Official Journal of the European Union remains. However, in order to ensure the presumption of conformity when there are not harmonised standards the Commission will be empowered to adopt technical specifications. This will be a fall-back option to be used only in cases the standardisation bodies are not able to provide standards or provide standards that do not respond to the Commission standardisation request and the essential health and safety requirements of Annex III.

Conformity assessment

The proposal keeps the manufacturer internal check option for machinery that is not classified as high risk. However, for high-risk machinery, considering that Annex I will be adapted to the technological progress when needed and the NLF alignment, only third party certification will be accepted, even when manufacturers apply the relevant harmonised standards.

The proposal updates the corresponding modules in line with the NLF Decision 768/2008/EC.

Notified bodies

Proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and for the confidence of all interested parties in the New Approach system. Therefore, in line with the NLF Decision, the proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the individual Member State.

Union market surveillance, control of machinery entering the union market and union safeguard procedure

The proposal integrates the NLF Decision 768/2008/EC provisions. This will reinforce the market surveillance and will clarify the safeguard close procedure. Commission decisions on measures taken by Member States on products placed on the EU market will be required only if other Member States disagree with such a measure, which will simplify Commission's work.

Essential health and safety requirements (EHSRs) traditional machinery:

The proposed Regulation adapts or adds following EHSRs to address specific machinery risks:

1.1.2. Principles of safety integration has been adapted to allow the machinery users to test the safety functions of the machinery**.**

1.6.1 on maintenance has been adapted to facilitate a timely and safe rescue when operators are trapped in the machine.

Digital documentation: EHSRs 1.7.4 on instructions and Annex V on the manufacturer's declaration of conformity allow that manufacturers provide digital instructions and the declaration of conformity. Nevertheless, a paper format is mandatory upon request.

EHSR 1.7.4 on instructions has been further adapted to request information on emissions of hazardous substances from the machinery and **EHSRs 2.2.1.1 and 3.6.3.1 on vibrations from portable handheld and hand-guided machinery** to adapt the instructions on vibrations in order to reduce the exposure occupational injury.

EHSR 2.2 on portable hand-held and/or hand-guided machinery is adapted to capture or reduce emissions of hazardous substances.

Section 3 on offset risks due to the mobility of machinery has been adapted to address the risks on **autonomous machines and remote supervisory stations.**

EHSR 3.2.2 seating for mobile machinery has been adapted to reinforce the drivers' safety.

EHSR 3.5.4 on risks of contact with live overhead power lines has been added to avoid the accidents when machinery makes contact with overhead lines.

EHSR 6.2 on control devices has been adapted allowing when possible on slow-speed lifts control devices other than hold-to-run to allow innovation.

Installation of lifting appliances: in view of facilitating market surveillance activities the manufacturer's **declaration of conformity** will add the address where the machine is permanently installed only for lifting machinery installed in a building or a structure.

Essential health and safety requirements machinery with new digital technologies:

The risk assessment that manufacturers must carry out before the machinery is placed on the market/ put into service will need to include also the risks appearing after the machinery is placed on the market due to its evolving and autonomous behaviour.

Cybersecurity with an impact on safety

In view of addressing, the risks stemming from malicious third party actions and that have an impact on the machinery safety the proposal adds a new **EHSR 1.1.9** and clarifies E**HSR 1.2.1** on safety and reliability of control systems.

Human-machinery interaction

Machines are becoming more powerful, autonomous and some look almost like humans, which requires adapting the EHSRs related to the contact between the human and the machinery i.e. **EHSRs 1.1.6** on ergonomics and **1.3.7** on risks related to moving parts and psychological stress.

Machinery with evolving capacity

Although AI system risks will be regulated by the Union legislation on AI, the proposal must ensure that the entire machinery is safe, considering the interactions between the machinery components including the AI systems. In this respect following EHSRs have been adapted: general principles, **1.1.6** on ergonomics, **1.2.1** on safety and reliability of control systems and **1.3.7** on risks related to moving parts and psychological stress.

Traceability of machinery safety

The safety of machinery increasingly relies on the software behaviour once the machinery has been placed on the market. In view of supporting the conformity assessment process and the

market surveillance, a few new requirements have been added in **EHSR 1.2.1** on safety and reliability of control systems and in the information required in the technical file in **Annex IV.**

Implementing acts

The proposal empowers the Commission to adopt, where appropriate, implementing acts to ensure the uniform application of this Regulation. Those implementing acts will be adopted in accordance with the provisions on implementing acts laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers.

Delegated acts

The proposal empowers the Commission to adopt delegated acts in order to adapt the list of high risk machinery in Annex I to take into account the progress of technical knowledge or new scientific evidence and the indicative list of safety components in Annex II.

Evaluation and review

The Commission will monitor the implementation, the application and the compliance to these new provisions with a view to assessing their effectiveness. The regulation requests a regular Commission's evaluation and review and the submission of a public report in this respect to the European Parliament and to the Council.

Final provisions

The proposed Regulation will become applicable 30 months after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements. However, the safeguard clause procedure needs to be applied shortly after the entry into force of this Regulation to simplify the mechanism. Transitional provisions are foreseen for products manufactured and the certificates issued by notified bodies under Directive 2006/42/EC so as to allow stocks to be absorbed and ensure a smooth transition to the new requirements. Directive 2006/42/EC will be repealed and replaced by the proposed Regulation.

2021/0105 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on machinery products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Whereas:

(1) Directive 2006/42/EC[2] of the European Parliament and of the Council was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for machinery in all Member States and to remove obstacles to trade in machinery between Member States.

(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Union economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance. Against this background and in view of the forthcoming implementation of the new EU strategic framework on health and safety at work 2021-2027 and its 'vision zero' approach to work-related deaths, one of the objectives of this Regulation is to set out ambitious occupational health and safety requirements for machinery products.

(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 machinery products may be made available on the market.

(4) Since the rules setting out the requirements for machinery products, in particular the essential health and safety requirements and the conformity assessment procedures,

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1 OJ C […], […], p. […].

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

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, notably in relation to the risks arising out of the use of machinery. For the avoidance of doubt, domestic animals should be considered to include farm animals.

(5a) A high-level of occupational health and safety (OHS) requirements is essential to ensure good working conditions and safe workplaces. Participation of workers and their representatives is crucial to protect workers' health and safety, including when installing and operating machinery products. Employers, trade unions and workers' representatives play an important role in implementing and monitoring OHS requirements at the workplace. They should be closely involved in all relevant phases when it comes to risk assessments and occupational health and safety policies.

(6) Regulation (EC) No 765/2008 of the European Parliament[3] lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking. That Regulation should be applicable to machinery products covered by this Regulation in order to ensure that those products, which are benefiting from the free movement of goods within the Union, fulfil requirements providing a high level of protection of public interests such as the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.

(7) Regulation (EC) No 2019/1020 of the European Parliament and of the Council[4] sets out rules on market surveillance and control of products entering the Union market. That Regulation already applies to machinery, since Directive 2006/42/EC is listed in its Annex I.

(7a) Article 4 of Regulation (EU) No 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, machinery products covered by this Regulation are to be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in Article 4 of Regulation (EU) No 2019/1020 in their respect.

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

[4] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L169, 25.6.2019, p. 1.)

(8) Decision No 768/2008/EC of the European Parliament and of the Council[5] lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the rules on presumption of conformity, the rules on EU declaration of conformity, the rules on CE marking, the requirements for conformity assessment bodies, the rules on notification procedures and conformity assessment procedures and the rules on procedures to deal with machinery products presenting a risk should be adapted to the reference provisions laid down in that Decision.

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

(10) Where there is a possibility that the machinery products will be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account of the fact that the consumer does not have the same knowledge and experience with handling machinery products in the design and construction of the products and should consider the safety implications, accordingly. The same applies where a machinery product is normally used to provide a service to a consumer.

(11) Recently, more advanced machines, which are less dependent on human operators, have been introduced on the market. These machines, known as collaborative robots or cobots, are working on defined tasks and in structured environments, yet they can learn to perform new actions in this context and become more autonomous. Further refinements to machines, already in place or to be expected, include real-time processing of information, problem solving, mobility, sensor systems, learning, adaptability, and capability of operating in unstructured environments (e.g. construction sites). The Commission Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics[6], states that the emergence of new digital technologies, like artificial intelligence, the Internet of things and robotics, raises new challenges in terms of product safety. The report concludes that the current product safety legislation, including Directive 2006/42/EC, contains a number of gaps in this respect that need to be addressed. Thus, this Regulation should cover the safety risks stemming from new digital technologies.

(12) In order to ensure protection of the health and safety of persons, domestic animals, property and, where applicable, the environment, this Regulation should apply to all forms of supply of machinery products, including distance selling as referred to in Article 6 of Regulation (EU) 2019/1020.

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5 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.08.2008, p. 82).

6 Report from the Commission to the European parliament, the Council and the European economic and social committee on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics (COM/2020/64 final)..

(13) In order to ensure legal certainty for all users, 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.

(14) In order to avoid legislating twice the same product, is appropriate to exclude from the scope of this Regulation weapons, including firearms that are subject to Directive (EU) 2017/853 of the European Parliament and of the Council[7].

(15) Since the purpose of this Regulation is to address the risks stemming from ~~the~~ machinery function and not the transport of goods, ~~or~~ persons or animals, it should not apply to vehicles the ~~which~~ only objective of which is the mere transport of animals by ~~goods or persons on~~ road, ~~by~~ air, on water or on rail networks, or transport of goods or persons by air, water or rail, regardless of the speed limits. ~~–~~However, machinery mounted on such vehicles or mobile machinery intended for facilitating works such as in construction sites or warehouses e.g. dumpers and forklifts, have a machinery function and should therefore be covered by this Regulation. Furthermore, non-type-approved, off-road vehicles, as well as e-bikes, cargo e-bikes, e-scooters and similar means of transport should also be covered by this Regulation as regards their machinery function, with the exception of road circulation risks, until such time as those means of transport become the subject of specific Union legislation. Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council[8] and Regulation (EU) No 168/2013 of the European Parliament and of the Council[9] respectively, they should be excluded from the scope of this Regulation.

(16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and ~~electronic~~ electric motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council[10] and should therefore be excluded from the scope of this Regulation. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council[11]as radio equipment. Those products should also be excluded from the scope of this Regulation.

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

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

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

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

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

(17) The evolution of the machinery sector has resulted in the growing use of digital means and software plays a more and more important role in the machinery design. Consequently, the definition of machinery should be adapted. In this respect, machinery missing only the upload of a software intended for the specific application of the machinery should fall under the definition of machinery and not under the definition of partly completed machinery. Furthermore, the definition of safety components should cover not only physical devices but also digital devices. In order to take into account the increasing use of software as a safety component, software that performs a safety function and is placed independently on the market should be considered a safety component.

(18) Partly completed machinery is a machinery product which must undergo further construction in order to be able to perform its specific application, i.e. the well-defined operations for which the machinery 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 machinery product as a whole, it is nevertheless important that the free movement of such partly completed machinery be guaranteed by means of a specific procedure.

(19) Where machinery products pose risks that are addressed by the essential health and safety requirements set out in this Regulation but are also wholly or partly covered by other more specific Union legislation, this Regulation should not apply to the extent that those risks are covered by that other Union legislation. In other cases, machinery products may pose risks that are not covered by the essential health and safety requirements set out in this Regulation. For example, machinery products incorporating a Wi-Fi function ~~or an artificial intelligence system~~ may pose risks not addressed by the essential health and safety requirements set out in this Regulation, as this Regulation does not deal with risks specific to such systems. ~~For artificial intelligence systems, the specific Union legislation on artificial intelligence should apply, since it contains specific safety requirements for high-risk artificial intelligence systems. In order to avoid incoherence with regard to the type of conformity assessment and to avoid introducing requirements to perform two conformity assessments, those specific safety requirements should however be checked as part of the conformity assessment procedure set out in this Regulation. The essential health and safety requirements set out in this Regulation should in any case be applied in order to ensure, where applicable, the safe integration of the artificial intelligence system into the overall machinery, so as not to compromise the safety of the machinery product as a whole.~~

(20) For trade fairs, exhibitions and similar events, it should be possible to exhibit machinery products which do not meet the requirements of this Regulation, since this would not pose any safety risk. However, for the sake of transparency, interested parties should be properly informed that the machinery products are not compliant and cannot be purchased.

(21) The evolution of the state of the art in the machinery sector has an impact on the classification of ~~high-risk~~ machinery products. ~~In view of~~ With a view to properly reflecting all ~~high-risk~~ machinery products and the hazards thereof, criteria should be established for the assessment by the Commission of which machinery products should be ~~included~~ added to~~in~~ the list of ~~high-risk~~ machinery products that should be subject to a specific conformity assessment procedure.

(22) Other risks related to new digital technologies are those provoked by malicious third parties that have an impact on the safety of machinery products. In this respect, manufacturers should be required to adopt proportionate measures which are limited to the protection of the safety of the machinery product. This does not preclude the application to machinery products of other Union legislation specifically addressing cybersecurity aspects.

(23) In order to ensure that machinery products, when placed on the market or put into service, do not entail health and safety risks for persons or domestic animals and do not cause harm to property and, where applicable, the environment, essential health and safety requirements should be set out which have to be met in order for the machinery products to be allowed on the market. Machinery products should comply with the essential health and safety requirements when placed on the market or put into service. Where such machinery products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer and that may imply that it no longer meets the relevant essential health and safety requirements, the modification should be considered as substantial. However, repair and maintenance operations which do not affect the machinery product's compliance with the relevant essential health and safety requirements should not be considered to be substantial modifications. For example, users may upload software in a machinery product that is not foreseen by the manufacturer and that may generate new risks. A change to the hardware or software in a machinery product might change its intended functions, type or performance, which might change the nature of the hazard or increase the level of risk In order to ensure the compliance of such a machinery 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 machinery product on the market or putting it into service. That requirement should only apply with respect to the modified part of the machinery product, provided that the modification does not affect the machinery product as a whole. ~~–~~In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the machinery product that are not impacted by the modification. It should be up to the person who carries out the substantial modification to demonstrate that the modification does not have an impact on the machinery product as a whole.

(24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to avoid unnecessary burdens ~~reduce the regulatory burden~~ on SMEs, notified bodies should simplify and facilitate procedures~~adapt the fees for conformity assessments and reduce them proportionately to the specific interests and needs of SMEs~~. The health and safety requirements set out in this regulation should apply equally to all undertakings.

(25) Economic operators should be responsible for the compliance of machinery products 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 health and safety of persons, in particular consumers and professional operators, [in particular workers and users,] where appropriate, domestic animals and property and, where applicable, the environment, as well as the fair competition on the Union market.

(26) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only machinery

products, which are in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations, which correspond to the role of each economic operator in the supply and distribution chain.

(27) In order to facilitate communication between economic operators, market surveillance authorities and users, Member States should encourage economic operators to include a website address in addition to the postal address.

(28) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

(29) The manufacturer or the manufacturer's authorised representative should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. ~~Where~~ The risk assessment should also address future updates or developments of software installed in the machinery product ~~integrates an artificial intelligence system~~ which were foreseen when the machinery product was placed on the market or put into service.~~,~~ ~~t~~The risks identified during the risk assessment should include those risks that may appear during the machinery product's lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. ~~In this respect, where the machinery product integrates an artificial intelligence system, the risk assessment for the machinery product should consider the risk assessment for that artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council+.~~

(30) The safety of the integral machinery product relies on the dependencies and interactions between its components and partly completed machinery and individual machinery that participate in a coordinated assembly of a machinery system. Therefore, manufacturers should be required to assess all those interactions in the risk assessment. The risk assessment should also address future updates or developments of a software installed in the machinery product, which are foreseen when the machinery product is placed on the market.

(31) It is essential that, before drawing up the EU declaration of conformity, the manufacturer ~~or the manufacturer's authorised representative established in the Union~~ prepares a technical documentation~~construction~~ file, which they should be required to make available to national authorities or notified bodies on request. Detailed plans of subassemblies used for the manufacture of the machinery product should only be required as part of the technical documentation ~~construction~~ file where knowledge of such plans is essential for assessing conformity with the essential health and safety requirements set out in this Regulation.

(32) It is necessary to ensure that machinery products from third countries entering the Union market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, in particular consumers and professional operators, [in particular workers and users,] where appropriate, domestic animals and property

~~+ OJ: Please insert in the text the number of the Regulation contained in document … .~~

and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such machinery products. Provision should therefore be made for importers to ensure that machinery products that they place on the market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the competent national authorities.

(33) As the distributor makes machinery products available on the market after they have been placed on the market by the manufacturer or the importer, the distributor should act with due care to ensure that his or her handling of the machinery product does not adversely affect its compliance with the requirements set out in this Regulation.

(34) When placing machinery products on the market, the importer should indicate on the machinery product his or her name, registered trade name or registered trade mark, the e-mail address and the postal address at which he or she can be contacted. Exceptions should be provided for in cases where the size or nature of the machinery product does not allow it. This includes cases where the importer would have to open the packaging to put his or her name and address on the machinery product.

(35) In view of ensuring the health and safety of the users of the machinery product, economic operators should ensure that all relevant documentation, such as the user's instructions, whilst containing precise and comprehensible information, is easily understandable and available in a language which can be easily understood by end-users, as determined by the Member State concerned [and available in all relevant languages], takes into account technological developments and changes to end-user behaviour, and is as up to date as possible. When machinery products are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.

(36) Any economic operator who either places a machinery product on the market under his or her own name or trademark or modifies a machinery product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(37) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the machinery product concerned.

(38) Ensuring traceability of machinery products 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 machinery products for a certain period of time. However, that obligation should be proportionate to the role of each economic operator in the supply chain and the economic operators should not be required to update information that they have not produced.

(39) This Regulation should ~~be limited to setting out the essential~~ set out health and safety requirements, supplemented by a number of more specific requirements for certain categories of machinery products. 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 machinery which is in conformity with harmonised standards that are developed and which references are published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council[12] for the purpose of expressing detailed technical specifications of those requirements.

(39a) The Commission in cooperation with the European Agency for Safety and Health at work (EU-OSHA) should establish an alert mechanism in the existing institutional structure to identify OSH related shortcomings of this Regulation at an early stage in the future, especially in the context of digitalisation and Artificial Intelligence. Moreover, the Commission should upgrade and extend the injury database (IDB)1, covering all types of injuries linked to the use of machinery products, to monitor risks. The involvement of social partners is essential in both cases. [Footnote:]https://ec.europa.eu/health/system/files/2020-12/idb_flyer_en_0.pdf]

(40) In the absence of relevant harmonised standards, the Commission should be able on an exceptional basis to establish technical specifications for ~~the essential~~ health and safety requirements provided that in doing so it duly respects the standardisation organisations' role and functions. Recourse to technical specifications should be used as a fall back solution to facilitate the manufacturer's obligation to comply with the health and safety requirements, for instance when the standardisation process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of a harmonised standard. Such delays could for example occur when the required quality is not reached.

(41) Compliance with harmonised standards and with technical specifications established by the Commission should be voluntary but should be considered as guidance. Alternative technical solutions should therefore be acceptable where compliance of the machinery with ~~the relevant essential~~ health and safety requirements is demonstrated in the technical file.

(42) ~~The essential h~~Health and safety requirements should be satisfied in order to ensure that the machinery product is safe. Those requirements should be applied with discernment to take account of the state of the art and the foreseeable risks at the time of construction and of technical and economic requirements.

(43) In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of machinery products, this Regulation should include ~~essential~~ health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to and in accordance with

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

Article 54(3) of Regulation (EU) 2019/881 of the European Parliament and of the Council[13].

(44) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not satisfy or entirely satisfy the requirements of this Regulation.

(45) The list of ~~high-risk~~ machinery in Annex IV to Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of that machinery. Nevertheless, the machinery sector embraces new ways of designing and constructing machinery products that may imply high risks, regardless of such intended use or any reasonably foreseeable misuse. For example, software ensuring safety functions of machinery based on artificial intelligence, embedded or not in the machinery product, should be classified as a potentially high-risk machinery product due to the characteristics of artificial intelligence such as data dependency, opacity, autonomy and connectivity, which might increase very much the probability and severity of harm and seriously affect the safety of the machinery product. ~~Furthermore, the market for software ensuring safety functions of machinery products based on artificial intelligence is so far very small, which results in a lack of experience and data. Furthermore, the market for software ensuring safety functions of machinery products based on artificial intelligence is so far very small, which results in a lack of experience and data.~~ Therefore, the conformity assessment of software ensuring safety functions based on artificial intelligence and machine learning should be carried out by a third party.

(45a) Nevertheless, provisions related to the conformity assessment of software ensuring safety functions set out in this Regulation should only apply to AI systems with a self-determining and evolving behaviour during normal operation that are developed through any machine learning techniques and approaches. On the contrary, those provisions should not apply to conventional software incapable of learning or evolving, and programmed only to execute certain automated functions of machinery products.

(46) Manufacturers should draw up an EU declaration of conformity to provide information on the conformity of machinery products with this Regulation. Manufacturers may also be required to draw up an EU declaration of conformity by other Union legislation. To ensure effective access to information for market surveillance purposes, a single EU declaration of conformity should be drawn up in respect of all Union acts. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.

(46a) The harmonised standards relevant to this Regulation should take into account the requirements of Directive (EU) 2019/882 (European Accessibility Act) and the United Nations Convention on the Rights of Persons with Disabilities. [Footnote 1a: OJ L 23, 27.1.2010, p. 35.]

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

(47) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on machinery products should be laid down in this Regulation.

(48) The CE marking should be the only marking, which guarantees that machinery products comply with the requirements of this Regulation. Member States should therefore take appropriate action as regards other markings which are likely to mislead third parties as to the meaning or the form of the CE marking.

(49) In order to enable economic operators to demonstrate and the competent authorities to ensure that machinery made available on the market is in conformity with the essential health and safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.

(50) Manufacturers should be responsible for ensuring that a ~~certifying the~~ conformity assessment is carried out in respect of their machinery products in accordance with this Regulation. Nevertheless, for certain types of machinery products that have a higher risk factor, a stricter conformity assessment ~~certification~~ procedure requiring the participation of a notified body could be applied~~should be required~~.

(51) It is essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(52) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.

(53) In order to ensure a consistent level of quality in the performance of conformity assessment of machinery products, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(54) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(55) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(56) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the machinery to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.

(57) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(58) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(59) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Union legislation. It is therefore appropriate to put in place a legal framework within which market surveillance can be carried out in an appropriate manner.

(60) Member States should take all appropriate measures to ensure that machinery products covered by this Regulation may be placed on the market only if, when properly installed and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons in particular consumers and professional operators, [in particular workers and users], and, where appropriate, domestic animals and property and, where applicable, the environment. Machinery products covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour. Nevertheless, reasonable anticipation of potentially hazardous development and use should be foreseen to assess compliance with health and safety requirements.

(61) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on machinery products and the safeguard clause relating to machinery products.

(62) Directive 2006/42/EC already provides for a safeguard procedure, which is necessary to allow for the possibility of contesting the conformity of machinery products. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(63) The existing safeguard procedure should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to machinery products posing a risk to the health or safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment. It

should allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such machinery products.

(64) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(65) In order to take into account technical progress and knowledge or new scientific evidence and to ensure a sufficient level of data availability, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the list of ~~high risk~~ machinery products in Annex I and the indicative list of safety components in Annex II, and of supplementing the obligations of Member States to communicate information on the categories of machinery products which are subject to a specific conformity assessment procedure. Where a new machinery product is added to the list in Annex I, the Commission should ensure that economic operators are provided with sufficient time to comply with their obligations under this Regulation.~~.~~ It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including with experts and stakeholders [social partners and other experts]~~at expert level~~. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing technical specifications for the ~~essential~~ health and safety requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons, in particular consumers and professional operators, [in particular workers and users] is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[14].

(67) The Commission should adopt immediately applicable implementing acts determining whether a national measure taken in respect of compliant machinery products that poses a risk is justified or not where, in duly justified cases relating to the protection of the health or safety of persons, imperative grounds of urgency so require.

(68) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

(69) When matters relating to this Regulation, other than its implementation or infringements, are being examined in a Commission expert group, the European

[14] 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).

Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

(70) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant machinery products are justified or not.

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

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

(73) Since the objective of this Regulation, namely to ensure that machinery products placed on the market fulfils the requirements providing for a high level of protection of health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of the need for harmonisation , be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(74) Council Directive 73/361/EEC[15] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks should be repealed as Directive 2006/42/EC took over its scope by including lifting accessories and chains and ropes.

(75) Directive 2006/42/EC has been amended several times. Since further substantial amendments are needed, and in order to ensure a uniform implementation of the rules on machinery products throughout the Union, Directive 2006/42/EC should be repealed.

(76) It is necessary to provide a~~for~~ sufficient and reasonable time frame~~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,~~

(76a) The harmonised standards relevant to this Regulation should take the United Nations Convention on the Rights of Persons with Disabilities) into account.

15 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. 51–55).

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down requirements for the design and construction of machinery products to allow the making available on the market or putting into service of machinery products, and establishes rules on the free movement of machinery products in the Union, ensuring a high level of protection for Union consumers and professional operators [ensuring a high level protection for all workers and other users].

Article 2

Scope

(1) This Regulation applies to the following machinery products

(a) machinery;

(b) interchangeable equipment;

(c) safety components;

(d) lifting accessories;

(e) chains, ropes, slings and webbing;

(f) removable mechanical transmission devices;

(g) partly completed machinery.

(2) This Regulation does not apply to:

(a) safety components that are intended to be used as spare parts to replace identical components and are supplied by the manufacturer of the original machinery product;

(b) specific equipment for use in fairgrounds or amusement parks;

(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;

(d) weapons, including firearms;

(e) vehicles which have as their only objective the transport of goods, ~~or~~ persons or animals by ~~road,~~ air, water or rail except for machinery mounted on those vehicles;

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

(f) two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) No 168/2013, except for machinery mounted on those vehicles;

(g) agricultural and forestry tractors~~vehicles~~, as well as systems, components, separate technical units, parts and equipment designed and constructed for such tractors~~vehicles~~, that fall within the scope of application of Regulation (EU) No 167/2013, except for machinery mounted on them;

(ga) motor vehicles exclusively intended for competition;

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

(i) machinery specially designed and constructed for military or police purposes;

(j) machinery specially designed and constructed for research purposes for temporary use in laboratories;

(k) mine winding gear;

(l) machinery intended to move performers during artistic performances;

(m) the following electrical and electronic products, insofar as they fall within the scope of application of Directive 2014/35/EU or Directive 2014/53/EU :

(i) household appliances intended for domestic use which are not electrically operated furniture;

(ii) audio and video equipment;

(iii) information technology equipment;

(iv) office machinery;

(v) low-voltage switchgear and control gear;

(vi) electric motors;

(n) the following high-voltage electrical products:

(i) switch gear and control gear;

(ii) transformers.

Article 3

Definitions

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

(1) ‘machinery’ means:

(a) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;

(b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion;

(c) an assembly referred to points (a) and (b), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure;

(d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (~~7~~10) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;

(e) an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for ~~its~~ the specific application foreseen by the manufacturer.

(1a) 'machinery product' means 'machinery', 'interchangeable equipment', a 'safety component', a 'lifting accessory', 'chains', 'ropes', 'slings', 'webbing', a 'removable mechanical transmission device' and 'partly completed machinery';

(1a) When machinery contains embedded software, preinstalled or installed subsequently, the latter shall be considered as an integrated part of the machinery;

(2) 'interchangeable equipment' means a device which, after the putting into service of ~~a~~ machinery ~~product~~, is assembled with that machinery ~~product~~ by the operator himself or herself in order to change its function or attribute to it a new function, in so far as that equipment is not a tool;

(3) 'safety component' means a physical or digital component, including software, of a machinery product with the exception of partly completed machinery, which is designed or intended ~~serves~~ to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the machinery to function or may be substituted by normal components in order for the machinery to function;

(3a) 'safety function' means a protective measure, designed to eliminate, or, if that is not possible, to reduce, a risk;

(4) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market, including slings and their components;

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

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

(7) 'slings' means slings 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 another machine by joining them at the first fixed bearing;

(10) ‘partly completed machinery’ means an assembly which is machinery but ~~for the fact that it~~which cannot in itself function so as to perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery product;

(11) ‘making available on the market’ means any supply of a machinery product 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 machinery product on the Union market;

(13) ‘putting into service’ means the first use, for its intended purpose, in the Union, of a machinery product;

(14) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;

~~(15) ‘artificial intelligence system’ means an artificial intelligence system as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and of the Council[+]~~

(16) ‘substantial modification’ means a modification of a machinery product, with the exception of partly completed machinery, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer and not addressed in the initial risk assessment, and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements ~~may be~~is affected;

(17) ‘manufacturer’ means any natural or legal person who manufactures machinery products or who has machinery products designed or manufactured, and (i) markets those machinery products under his or her name or trademark or (ii) uses ~~who designs and constructs~~ machinery products for his or her own purposes in the course of his or her business~~use~~;

(18) ‘instructions for use’ means the information provided by the manufacturer when the machinery product, with the exception of partly completed machinery, is placed on the market or put into service to inform the user of the machinery product of the intended ~~purpose and the~~and proper use of that machinery product as well as information on any precautions to be taken when using or installing the machinery product, including information on the safety aspects and on how to keep that machinery product safe and ensure that it remains “fit for purpose” during its entire lifetime;

(19) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;

~~[+] OJ: Please insert in the text the number of the Regulation contained in document … and insert the number, date, title and OJ reference of that Regulation in the footnote."~~

(20) ‘importer’ means any natural or legal person established within the Union who places machinery products 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 machinery products available on the market;

(22) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(23) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by machinery products;

(24) ‘harmonised standard’ means a harmonised standard as defined in Article 2(1), point (c) of Regulation (EU) No 1025/2012;

(25) ‘CE marking’ means a marking by which the manufacturer indicates that a machinery product, with the exception of partly completed machinery, 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(11) of Regulation (EC) No 765/2008;

(28) ‘conformity assessment’ means the process demonstrating whether the essential health and safety requirements of this Regulation relating to machinery products, with the exception of partly completed machinery, have been fulfilled;

(29) ‘conformity assessment body’ means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;

(30) ‘notified body’ means a conformity assessment body notified in accordance with Article 24~~6~~ of this Regulation;

(31) ‘market surveillance authority’ means a market surveillance authority as defined in Article 3, point (4) of Regulation (EU) 2019/1020;

(32) ‘recall’ means any measure aimed at achieving the return of a machinery product that has already been made available to the end-user;

(33) ‘withdrawal’ means any measure aimed at preventing a machinery product in the supply chain from being made available on the market.

(33a) ‘lifetime’ means the period from the moment that a machinery product is placed on the market or put into service until the moment that it is discarded, including the effective time when the machinery product is capable of being used and the phases of transport, assembly, dismantling, disabling, scrapping or other physical or digital modifications foreseen by the manufacturer;

(33b) ‘professional operator’ means a natural person who uses or operates a machinery 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 or the putting into service of machinery 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 machinery product which does not comply with this Regulation, provided that a visible sign clearly indicates that it does not comply with this Regulation and will not be available on the market until it has been brought into conformity.

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

Article 4a

Free European Injury Database

1. The Commission shall upgrade and extend the European Injury Database (IDB), to collect information on all type of injuries linked to machinery products covered by this regulation.

2. The competent national authorities of Member States shall provide the Commission with the relevant data, in compliance with Union and national rules on data protection.

3. The Commission shall establish a common methodology for the collection of the data.

Article 5

Categories of ~~High-risk~~ machinery products subject to specific conformity assessment procedure

1. ~~High-risk m~~Machinery products that fall within the categories~~listed~~ in Annex I shall be subject to ~~a~~ the specific conformity assessment procedure, ~~as~~ referred to in Article 21(2) and (2a).

2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, after consulting the stakeholders concerned, in view of technical progress and knowledge or new scientific evidence by ~~including in~~ adding to the list of ~~high-risk~~categories of machinery products in Annex I a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.

3. A machinery product shall be ~~included in~~ added to the list of ~~high-risk~~ categories of machinery products in Annex I if it poses a risk to human health taking into account its design, ~~and~~ intended purpose and any foreseeable use [and foreseeable use.]. A machinery product shall be withdrawn from the list of ~~high-risk~~ categories of machinery products in Annex I if it no longer poses such risk. The risk posed by a

certain machinery product 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 shall be taken into account:

(a) the degree to which each affected person would be impacted by the harm;

(b) the number of persons potentially affected;

(c) the degree to which potentially affected parties are dependent on the outcome produced by the machinery product;

(d) the degree to which potentially affected parties are in a vulnerable position vis-à-vis the user of the machinery product;

(e) the degree of reversibility of the harm produced by the machinery product;

(f) the degree to which the machinery product has been used for a specific purpose;

(g) indications of harm that have been caused in the past by machinery products which have been used for a specific purpose.

4. The Commission shall thoroughly assess the criteria laid down in paragraph 3 on the basis of available information. In particular the following information shall be communicated to the Commission by the Member States ~~when it becomes available to them~~ in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph:

(a) an assessment of the risks as referred to in paragraph 3;

(b) a cost-effectiveness analysis;

(c) a machinery accident analysis;

(d) statistics on accidents caused by the machinery product for the preceding four years based, in particular information obtained from the Information and Communication System for Market Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX)~~–~~, the European Injury Database (EU-IDB) and the Machinery Administrative Cooperation Group reporting [and the European Injury Database].

By ... [the date of application of this Regulation referred to in Article 52], and every three years thereafter, Member States shall provide the information referred to in the first subparagraph.

4a. The Commission is empowered to adopt delegated acts in accordance with Article 45 to supplement paragraph 4 of this Article by specifying Member States' obligations to communicate information through the establishement of a common methodology on the assessment, analysis and statistics referred to in points (a) to (d), in order to ensure that a sufficient level of data availability for the Commission's assessment referred to in paragraph 4 is carried out.

4b. A machinery product that is established as posing a risk to human health according to paragraph 3 shall be included in the list of categories of machinery products in Annex I, Part A, if at least one of the following conditions is fulfilled:

(a) no harmonised standards or technical specifications covering all the relevant essential health and safety requirements exist for the category of the machinery product in question;

(b) residual risks due to shortcomings of protective measures exist and information communicated to the Commission in accordance with paragraph 4 demonstrates a recurrence of serious or fatal accidents or damage to health in relation with these residual risks;

(c) statistics on accidents referred to in paragraph 4 demonstrate either shortcomings in the relevant harmonised standards or technical specifications or a recurring incorrect application of the relevant harmonised standards or technical specifications;

(d) the degree of uncertainty of the potential risk related to new types of machinery or technologies.

A machinery product that is established as posing a risk to human health in accordance with paragraph 3 and which does not fullfil any of the conditions set out in the first subparagraph shall be included in the list of catageories of machinery products in Annex I, Part B, without prejudice to Article 11 of Regulation (EU) No 1025/2012 on formal objections to harmonised standards.

The Commission, when establishing whether a machinery product poses a risk to human health in accordance with paragraph 3 shall inter alia take into account the information communicated to it pursuant to paragraph 4.

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

Article 6

Safety components

1. An indicative list of safety components is set out in Annex II.

2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex II in view of technical progress and knowledge or new scientific evidence by including a new safety component in the indicative list of safety components or withdrawing an existing safety component from that list.

3. The Commission shall thoroughly assess the risks that require the inclusion of a new safety component in the list of safety components in Annex II or a withdrawal of a safety component from that list.

4. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately inform the Commission of its concerns and provide reasons in support thereof.

Article 7

Requirements for machinery products

1. Machinery products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended purpose or under

conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III.

1a. Partly completed machinery shall only be made available on the market if it satisfies the applicable essential health and safety requirements set out in Annex III and the manufacturer has declared this to be the case in the EU declaration of incorporation.

Article 8

Specific Union harmonisation legislation

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

~~*Article 9*~~

~~***Regulation (EU) .../... of the European Parliament and of the Council+***~~

~~Where machinery products contain an artificial intelligence system, to which the essential health and safety requirements of Regulation (EU) …/… apply, this Regulation shall, in relation to that artificial intelligence system, only apply with regard to its safe integration into the overall machinery, so as not to compromise the safety of the machinery product as a whole.~~

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 10

Obligations of manufacturers

1. When placing a machinery product on the market or putting it into service, manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III.

2. Before placing a machinery product on the market or putting it into service, manufacturers shall draw up the technical documentation referred to in Annex IV ('technical documentation') and carry out the relevant conformity assessment procedures referred to in Article 21 or Article 22 or have them carried out.

   Where compliance of the machinery 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

~~+ OJ: Please insert in the text the number of the Regulation contained in document … .~~

in accordance with Article 18 and affix the CE marking in accordance with Article 20, except for partially completed machinery.

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

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

   When deemed appropriate with regard to the risks presented by machinery products, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of machinery products made available on the market or put into service, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery products and machinery product recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that the machinery products which they place on the market or put into service bear ~~bears~~ a type, batch or serial number or other element allowing its identification, or, where the size or nature of the machinery product does not allow it, that the required information is provided on the packaging or in a document accompanying the machinery product.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and the website or email address at which they can be contacted on the machinery product or, where that is not possible, on its packaging or in a document accompanying the machinery 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 end-users and market surveillance authorities.

7. Manufacturers shall ensure that the machinery products are accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information shall be clear, understandable, intelligible and legible.

8. Manufacturers shall either provide the EU declaration of conformity with the machinery product or include in the instructions and information set out in section 1.7 of Annex III the internet address at which the EU declaration of conformity can be accessed.

9. Manufacturers who consider or have reason to believe that a machinery product, which they have placed on the market or put into service is not in conformity with the essential health and safety requirements set out in Annex III shall immediately take the corrective measures necessary to bring that machinery product into

conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery product available on the market or put into service to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery product with the essential health and safety requirements set out in Annex III, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks posed by the machinery product, which they have placed on the market or put into service.

Article 11

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

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

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

   (a) keep the EU declaration of conformity and the technical documentation electronically at the disposal of the national market surveillance authorities for ten years after the machinery 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 machinery product. It could be either in paper or electronic form;

   (c) cooperate with the competent national authorities, at their request, on any measures taken to eliminate the risks posed by a machinery product covered by the authorised representative's mandate.

Article 12

Obligations of importers

1. Importers shall only place on the market machinery products that comply with the essential health and safety requirements set out in Annex III.

2. Before placing a machinery product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 or Article 22 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the machinery product bears the CE marking referred to in Article 19 and is accompanied by the required documents, and

that the manufacturer has complied with the requirements set out in Article 10(5) and (6).

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

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

4. Importers shall ensure that the machinery product is accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned.

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

6. When deemed appropriate with regard to the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, presented by a machinery product, importers shall carry out sample testing of machinery products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery products and machinery products recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a machinery product, which they have placed on the market, is not in conformity with the essential health and safety requirements set out in Annex III shall immediately take the corrective measures necessary to bring that machinery product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, importers shall immediately inform the competent national authorities of the Member States in which they made the machinery product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

8. Importers shall, for ten years after the machinery 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 can be made available to those authorities. Where relevant, the source code or programmed logic included in the technical documentation shall be made available upon a reasoned request from competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form,

necessary to demonstrate the conformity of the machinery product with the essential health and safety requirements set out in Annex III in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment posed by a machinery product, which they have placed on the market.

Article 13

Obligations of distributors

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

2. Before making a machinery product available on the market, distributors shall verify that:

   (a) the machinery product bears the CE marking;

   (b) the machinery product is accompanied by the required documents and by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users in the Member State in which the machinery product is to be made available on the market;

   (c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.

3. Where a distributor considers or has reason to believe that a machinery product is not in conformity with the essential health and safety requirements set out in Annex III, the distributor shall not make the machinery product available on the market until it has been brought into conformity. Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the distributor shall inform the manufacturer and the market surveillance authorities to that effect.

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

5. Distributors who consider or have reason to believe that a machinery product, which they have made available on the market, is not in conformity with the essential health and safety requirements set out in Annex III shall make sure that the corrective measures necessary to bring that machinery product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery product with the essential health and safety requirements set out in Annex III in a language that can be easily

understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, posed by a machinery product, which they have made available on the market.

Article 14

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 where that importer or distributor places a machinery product on the market under his or her name or trademark or carries out a substantial modification of a machinery product that has already been placed on the market or put into service.

Article 15

Other cases in which obligations of manufacturers apply

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the machinery product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the part of the machinery product that is affected by the modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product.

Article 16

Identification of economic operators

1. Economic operators shall, on request, identify the following to the market surveillance authorities:

   (a) any economic operator who has supplied them with a machinery product;

   (b) any economic operator to whom they have supplied a machinery product.

2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the machinery product and for ten years after they have supplied the machinery product.

CHAPTER III

CONFORMITY OF THE MACHINERY

Article 17

Presumption of conformity of machinery products

1. A machinery product which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those standards or parts thereof.

2. The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III.

3. The Commission is empowered to adopt implementing acts establishing technical specifications for the essential health and safety requirements set out in Annex III where the following conditions have been fulfilled:

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

   (b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements the requested standard has not been developed within three years following ~~and there are undue delays in~~ the standardisation ~~procedure~~ request or the request has not been accepted by any of the European standardisation organisations.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3). [The Commission shall also consult relevant stakeholders, including social partners in this context.]

   The Commission shall duly consult all relevant stakeholders.

4. A machinery product which is in conformity with the technical specifications 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 technical specifications or parts thereof.

4a. If harmonised standards covering the essential health and safety requirements set out in Annex III are developed and the references to them are published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, the relevant technical specifications shall no longer apply.

5. Machinery products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU) 2019/881 and the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1,

as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.

Article 18

EU declaration of conformity

1. The EU declaration of conformity shall be able to be completed electronically and 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, shall contain the elements specified in the relevant modules set out in Annexes VI, VII, VIII and IX ~~and shall be continuously updated~~. It shall be translated into the language or languages required by the Member State in which the machinery product is placed on the market or is made available on the market.

3. Where a machinery product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery product with the requirements laid down in this Regulation.

Article 19

General principles of the CE marking

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

Article 20

Rules for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery product. Where that is not possible or not warranted on account of the nature of the machinery product, it shall be affixed to the packaging and to the documents accompanying the machinery product.

2. The CE marking shall be affixed before the machinery product is placed on the market.

3. For a machinery product in the conformity assessment of which a notified body participates in accordance with Annex IX, the CE marking shall be followed by the identification number of that notified body.

   The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.

4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating a special risk or use.

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER IV

CONFORMITY ASSESSMENT

Article 21

Conformity assessment procedures for machinery products except partly completed machinery

1. In order to certify the conformity of a machinery product with this Regulation, the manufacturer or its authorised representative and the person who has carried out a substantial modification to the machinery product, shall apply one of the procedures for assessment of conformity referred to in paragraphs 2 and 3.

2. Where the machinery product is a ~~high-risk~~ machinery product listed in Annex I, part A, the manufacturer or the manufacturer's authorised representative and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:

   (a) EU type-examination procedure (module B) provided for in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;

   (b) Conformity based on full quality assurance (module H) set out in Annex IX.

2 a. Where the machinery product is a machinery product listed in Annex I, part B, and has been manufactured in accordance with harmonised standards or technical specifications covering all the relevant essential health and safety requirments, the manufacturer and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:

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

   (b) the EU type-examination procedure (module B) provided for in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;

   (c) conformity based on full quality assurance (module H) set out in Annex IX.

3. Where the machinery product is not a ~~high-risk~~ machinery product listed in Annex I, the manufacturer ~~or the manufacturer's authorised representative~~ and the person who has made a substantial modification to the machinery product shall apply the internal production control procedure (module A) set out in Annex VI.

4. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment ~~and reduce those fees proportionately to their specific interests and needs~~.

Article 22

~~Conformity assessment p~~Procedures for partly completed machinery

1. The manufacturer of partly completed machinery ~~or the manufacturer's authorised representative~~ shall, before placing partly completed machinery on the market, ensure that the following documents are drawn up, in paper or electronic form:

   (a) the relevant technical documentation that satisfies the requirements laid down in Annex IV, part B;

   (b) assembly instructions that satisfy the requirements laid down in Annex X;

   (c) the EU declaration of incorporation that has the model structure set out in Annex V.

2. Where relevant, the manufacturer of partly completed machinery ~~or the manufacturer's authorised representative~~ shall make available to the competent national authority upon its request the source code or programmed logic included in the technical documentation referred to in paragraph 1, point (a)~~,~~, provided that it is needed in order for that authority to be able to check compliance with the essential health and safety requirements set out in Annex III. The assembly instructions referred to in paragraphs 1, point (b), and the EU declaration of incorporation referred to in paragraph 1, point (c), shall accompany the partly completed machinery until it is incorporated into the final machinery product and shall afterwards form part of the technical file for that machinery product.

Article 23

Protection of persons during installation and use of machinery products

Member States may lay down requirements, including those concerning the availability of training sessions, sufficient resources and equipment, to ensure that persons, including workers, are protected when installing and using machinery products, provided that such rules do not allow for modification of a machinery product in a way that is not compatible with this Regulation.

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 24

Notification

Member States shall notify the Commission and the other Member States of conformity assessment bodies authorised to carry out conformity assessments in accordance with this Regulation.

Article 25

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 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 within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 26. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 26

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment of the machinery product.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 27

Information obligation on notifying authorities

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

The Commission shall make that information publicly available.

Article 28

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the machinery product it assesses.

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

4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, importer, distributor, installer, purchaser, owner, user or maintainer of a machinery product, that they assess, nor the authorised representative of any of those parties. This shall not preclude the use of a machinery product that is necessary for the operations of the conformity assessment body or the use of a machinery product 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 machinery 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 ~~activities~~ tasks mentioned in Annexes VII, VIII and IX and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

   At all times, and for each conformity assessment procedure and each kind of a machinery product 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 ~~activities~~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 activities that it carries out as a notified body and other ~~activities~~tasks;

(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.

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

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex III, of the applicable harmonised standards referred to in Article 17, and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.

8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment activities shall be guaranteed.

The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment activities 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 activities in accordance with Annexes VII, VIII and IX, except in relation to the competent authorities of the Member State in which its activities 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 activities are informed of, the

relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 29

Presumption of conformity of notified bodies

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

Article 30

Subsidiaries of and subcontracting by notified bodies

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

Article 31

Application for notification

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

Article 32

Notification procedure

1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 28.

2. The notifying authority shall send a notification to the Commission and the other Member States of each conformity assessment body referred to in paragraph 1, using the electronic notification tool developed and managed by the Commission.

3. The notification referred to in paragraph 2 shall include the following:

   (a) full details of the conformity assessment activities to be performed;

   (b) an indication of the conformity assessment module or modules and the kinds of machinery products concerned;

   (c) the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 28.

5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3).

   Only such a body shall be considered a notified body for the purposes of this Regulation.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.

Article 33

Identification numbers and lists of notified bodies

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

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

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

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

Article 34

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 28, or that it is failing to fulfil its obligations as set out in Article 35 the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 35

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying authority 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 authority to take the necessary corrective measures, including the withdrawal of the notification if necessary.

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

Article 36

Operational obligations of notified bodies

1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Annexes VII, VIII and IX.

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 machinery 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 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 the harmonised standards referred to in Article 17, or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity or adopt an approval decision

4. Where, in the course of the monitoring of conformity following the issuance of a certificate of conformity or the adoption of an approval decision, a notified body finds that a machinery product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate of conformity or the approval decision, if necessary.

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

Article 37

Appeals against decisions of notified bodies

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

Article 38

Information obligation on notified bodies

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

   (a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval decision;

   (b) any circumstances affecting the scope of, or the conditions for, its notification;

   (c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;

   (d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.

2. A notified body shall provide other notified bodies carrying out similar conformity assessment activities covering the same kinds of machinery product with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 39

Exchange of experience

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

Article 40

Coordination of notified bodies

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

A notified body shall participate in the work of that group, directly or by means of designated representatives.

CHAPTER VI

UNION MARKET SURVEILLANCE, CONTROL OF MACHINERY PRODUCTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 41

Procedure at national level for dealing with machinery products presenting a risk

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a machinery product covered by this Regulation does not comply with the requirements laid down in this Regulation or presents a risk to the health or safety of persons, and, where appropriate, domestic animals or to property and, where applicable, the environment, they shall carry out an evaluation in relation to the machinery 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 machinery product does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take ~~all~~ appropriate and proportionate corrective action, as provided for in Article 16(3) of Regulation (EU) 2019/1020, to bring the ~~machinery product into~~non-~~-~~compliance to an end~~with those requirements, to withdraw the machinery product from the market~~, or to eliminate the risk they specify ~~recall it~~ 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 all the machinery products concerned that the economic operator has made available on the market throughout the Union.

4. Where the relevant economic operator does not take ~~adequate~~ corrective action ~~within the period~~ referred to in paragraph 1, second subparagraph, within the specified period or where the non-compliance or the risk referred to in paragraph 1, first subparagrapgh, persists, the market surveillance authorities shall ensure that ~~take all appropriate provisional measures to prohibit or restrict~~ the machinery product concerned is withdrawn or recalled, or that making ~~being made~~ available on the ~~their national market, to withdraw the machinery product from that~~ market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly without delay.~~or to recall it.~~

~~The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.~~

5. The information referred to in paragraph 4~~, second subparagraph,~~ shall include all available details, in particular the data necessary for the identification of the non-compliant machinery product, the origin of that machinery product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:

(a) failure of the machinery product to meet the requirements relating to the essential health and safety requirements set out in Annex III;

(b) shortcomings in the harmonised standards referred to in Article 17(1);

(c) shortcomings in the technical specifications referred to in Article 17(4).

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the machinery product 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~~, second subparagraph,~~ no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the machinery product from the market, are taken in respect of the machinery product concerned without delay.

Article 42

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 41(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission

considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not.

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

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

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant machinery product is withdrawn from their market, and shall inform the Commission accordingly.

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

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

Article 43

Compliant machinery products which present a risk

1. Where, having carried out an evaluation under Article 41(1), a Member State finds that although a machinery product is in compliance with the essential health and safety requirements set out in Annex III, it poses a risk to the health and safety of persons and, where appropriate, domestic animals or to property and, where applicable, the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the machinery product concerned, when placed on the market, no longer presents that risk, to withdraw the machinery product from the market or to recall it within a reasonable period which is commensurate with the nature of the risk.

2. The economic operator shall ensure that corrective action is taken in respect of all the machinery products concerned that the economic operator has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the machinery product concerned, the origin and the supply chain of the machinery product, the nature of the risk involved and the nature and duration of the national measures taken.

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

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

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

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

Article 44

Formal non-compliance

1. Without prejudice to Article 41, where a Member State makes one of the following findings with regard to a machinery product, it shall require the relevant economic operator to put an end to the non-compliance concerned:

   (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Regulation;

   (b) the CE marking has not been affixed;

   (c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 20(3) or has not been affixed;

   (d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;

   (e) the technical documentation is either not available or not complete;

   (f) the information referred to in Article 10(6) or Article 12(3) is absent, false or incomplete;

   (g) any other administrative requirement provided for in Article 10 or Article 12 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the machinery product being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER VII

DELEGATED POWERS AND COMMITTEE PROCEDURE

Article 45

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Articles 5(2), 5(4a) and 6(2) shall be conferred on the Commission for a period of five years from … [*the date of entry*

into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

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

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

6. A delegated act adopted pursuant to Articles 5(2), 5(4a) and 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 46

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

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

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

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

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

CHAPTER VIII

CONFIDENTIALITY AND PENALTIES

Article 47

Confidentiality

1. All parties shall respect the confidentiality of the following information and data obtained in carrying out their tasks in accordance with this Regulation:

   (a) personal data;

   (b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless disclosure is in the public interest.

2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the competent national authorities and between competent national authorities and the Commission shall not be disclosed without the prior agreement of the originating competent national authority.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 48

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of this Regulation and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive and may include criminal penalties for serious infringements.

2. Member States shall notify those rules and those measures to the Commission by … [*24 months after the date of entry into force of this Regulation*] and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER IX

TRANSITIONAL AND FINAL PROVISIONS

Article 49

Repeals

1. Directive 73/361/EEC is repealed.

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

2. Directive 2006/42/EC is repealed with effect from … [~~30~~48 months after the date of entry into force of this Regulation].

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

Article 50

Transitional provisions

1. Member States shall not ~~until … [*42 months after the date of entry into force of this Regulation*]~~ impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before … [*the date of ~~entry into force~~application of this Regulation*]. However, Chapter VI of this Regulation shall apply *mutatis mutandis* to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [*the date of ~~entry into force~~application of this Regulation*].

2. EC type-examination certificates and approval decisions issued in accordance with Article 14 of Directive 2006/42/EC shall remain valid until ~~… [*42 months after the date of entry into force of this Regulation*], unless~~ they expire ~~before that date~~.

Article 51

Evaluation and review

1. By … [*72~~54~~ months after the date of entry into force of this Regulation*] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

2. Taking account of technical progress and practical experience gained in Member States as indicated in Article 5, the Commission shall in its report include an evaluation on the following aspects of this Regulation:

   (a) the essential health and safety requirements set out in Annex III;

   (b) the conformity assessment procedure applicable to high-risk machinery 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.

Article 52

Entry into force and application

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

It shall apply from … [48~~30~~ months after the date of entry into force of this Regulation].

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

Done at Brussels,

For the European Parliament *For the Council*