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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the

Proposal for a Regulation of the European Parliament and of the Council

on machinery products

{COM(2021) 202 final} - {SEC(2021) 165 final} - {SWD(2021) 82 final}

Executive Summary Sheet

Impact assessment on a proposal for a regulation of the European Parliament and of the Council on machinery.

A. Need for action

Why? What is the problem being addressed?

As part of the Commission Work Programme 2020 under the priority 'A Europe fit for the Digital Age', the Commission plans to revise the **Machinery Directive ('the MD', Directive 2006/42/EC).** This revision contributes to both the digital transition and to the strengthening of the single market. In February 2020, the Commission published a white paper on artificial intelligence accompanied by a report, *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*. The report concluded that the EU's current product-safety legislation – in particular the MD – contains a number of gaps that need to be addressed.

The general objectives of the MD are to: (i) ensure free movement of machinery within the single market; and (ii) ensure a high level of protection for machinery users and other exposed persons. The REFIT evaluation of the MD (SWD (2018)160) concluded that the Directive is generally relevant, effective, efficient and coherent. The evaluation also concluded that the MD has EU added value, but it argued that the MD needed specific improvements and simplification. The evaluation stated that the MD enables technological developments in the digital era, given that the MD is underpinned by the 'new approach' principles (the 'new approach' means that legislation sets mandatory basic requirements, leaving standardisers organisations to set the technical details needed to meet those requirements). However, the evaluation argued that further analysis of the MD is needed to assess its effectiveness and fitness for purpose in the future. This further analysis should cover developments in digitalisation, such as the internet of things, artificial intelligence (AI), and the new generation of autonomous robots.

In particular, the revision of the MD intends to address the following issues: (i) the MD does not sufficiently cover new risks originating from emerging technologies; (ii) legal uncertainty due to a lack of clarity on the scope and definitions; and possible safety gaps in traditional technologies; (iii) insufficient provisions for high risk machines; (iv) monetary and environmental costs due to extensive paper-based documentation; (v) inconsistencies with other pieces of Union product-safety legislation; and (vi) divergences in interpretation due to transposition.

What is this initiative expected to achieve?

The MD is a piece of product-safety legislation that aims to ensure a high level of protection for workers, consumers and other exposed persons by focusing on the safety of machinery itself, and thus imposing obligations on machinery manufacturers to design and construct inherently safe machinery (safety by design). This initiative intends to revise the MD so that it can continue fullfilling its objectives by: (i) ensuring a high level of safety and protection for users of machinery and other people exposed to it; and (ii) establishing a high level of trust in digital innovative technologies for consumers and users, thus ensuring a level playing field for economic operators and preserving the competitiveness of the machinery sector in global digital markets.

These general objectives translate into the following six specific objetives: (i) cover new risks related to digital emerging technologies; (ii) ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies; (iii) reassess machines considered as high risk and reassess related conformity procedures; (iv) reduce paper-based requirements for documentation; (v) ensure coherence with other NLF legislation; and (vi) reduce possible divergences in interpretation derived from transposition.

What is the value added of action at the EU level?

The machinery sector is a highly relevant part of the engineering industry and one of the industrial drivers of the EU economy. In 2017, the machinery sector recorded turnover of EUR 663 billion, production of EUR 609 billion, and a value added of EUR 191 billion. The total EU machinery and equipment exports amounted to EUR 503 billion, of which 49% were exported to EU Member States (i.e. intra-EU exports), while 51% were exported to countries outside the EU (extra-EU exports).

The MD is a key driver of safety for machinery users in the EU. As already mentioned, the main objectives of the MD are to ensure a high level of health and safety protection for these users, and to allow the free circulation of machinery in the EU. In particular, the MD helps reduce social costs by preventing accidents that may be caused by the use of machinery. A key rationale for an EU-level machinery directive is to provide harmonisation across Member States based on Article 114 TFEU. Any changes to the MD's scope or requirements must be made at EU level to avoid distorting the market, creating barriers to the free movement of products and undermining the protection of human health and well-being.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred

choice or not? Why?

There are four policy options. These are set out in the bullet points below.

- **Option 0 – No change**: The baseline scenario is 'no action'. This option would leave the existing standardisation process to develop as usual, without particular focus on risks stemming from emerging technologies, and with no particular focus on areas for improvement related to traditional technologies. This baseline option would also include revision of the *Guide to application of the Machinery Directive* ('the Guide') following the normal process (discussions among stakeholders and decision taken only by consensus).
- **Option 1 – Self-regulation by industry and changes to the Guide**: This option would make no changes to the current MD. Instead it would introduce clarifications to the Guide with a push for: (i) consensus on scope and definitions; (ii) reduction of paper-based documentation; (iii) clarifications on existing high-risk machinery; (iv) better coherence with other NLF product-safety legislation; and (v) fewer divergences in interpretations in the various Member States. On this last point, this option would also involve dedicated sessions of the Machinery Expert Group. New risks stemming from emerging technologies (as well as certain risks from traditional technologies) would be addressed through the issuance of a new Commission standardisation request, within the boundaries of the current legal text.
- **Option 2 – Burden minimisation**: This option would focus on clarifying the legal text and scope and achieving simplification. To this end, this option would change the current MD to increase legal clarity in scope and definitions. It would also make changes to achieve simplification by: (i) introducing to the legal text permission for instruction manuals to be issued in digital format; (ii) aligning the MD to the NLF; and (iii) avoiding divergences in interpretation by converting the MD into a regulation. Changes to the current act would also include an empowerment to the Commission for reviewing in the future the list of high-risk machines under certain criteria. However, all these changes would be made without adaptations to the safety requirements for products. There would therefore be no changes in the manufacturers' obligations for designing and manufacturing the machinery. This would be complemented by the issuance of a new Commission standardisation request, within the boundaries of the current safety requirements in legal text.
- **Option 3 – Burden minimisation and enhanced safety**: This option is the most ambitious, striving for a better safety while taking advantage of all burden reduction possibilities. To this end, this option would change the current act to increase legal clarity in scope and definitions. It would also make changes to achieve simplification by: (i) allowing digital documentation; (ii) aligning the MD to the NLF; and (iii) avoiding divergences in interpretation by converting the MD into a regulation. This option would also include an empowerment to the Commission for reviewing the current list of machines presenting high risks to new market developments in this area, remove the internal check option for the conformity assessment of the high risk machines, and make a first adaptation of the list of high risk machines. In addition, it would also adapt the safety requirements of Annex I with which manufacturers must comply when designing and manufacturing machinery, to address risks stemming from emerging technologies, as well as specific risks from traditional technologies. This would be complemented by the issuance of a new Commission standardisation request, taking into account any new and/or revised safety requirements in the legal text.

The **preferred policy option is option 3.** 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. It also ensures coherence with existing product-safety legislation, with the future regulation on artificial intelligence and with the Cybersecurity Act.

The preferred option adds new requirements and clarifies existing ones: (i) in a targeted and proportional way; and (ii) only when necessary. These new requirements and clarifications are often applicable to certain types of machinery only. The preferred option will add legal clarity to the current MD in its scope, definitions and requirements, including those requirements to cover risks stemming from emerging technologies. The preferred option will also be instrumental in properly driving the standardisation activities in a way that enhances safety and ensures a higher level of trust and industry competitiveness in the market (including the digital market). In addition, the preferred option: (i) empowers the Commission to adapt the current list of machines that present high risks to take account of new market developments in this area; (ii) removes the internal-check option for the conformity assessment of high-risk machines; and (iii) reviews the list of high-risk machines in full coherence with the new regulation on Artificial Intelligence. It proposes a burden-reduction measure highly requested by the industry and in line with the Commission digital policy, by allowing digital documentation (while at the same time granting end-users the possibility to request a printed version of the instruction manual free of charge at the moment of purchase). Finally, the revised MD will gain in coherence and legal certainty by being aligned to the NLF and becoming a regulation. To ensure proportionality, this policy option is complemented by: (i) a new standardisation request to be issued by the Commission; and (ii) a Guide for detailed clarifications.

Who supports which option?

Member State authorities, notified bodies, consumer associations, and workers' asociations mostly support option 3.

Manufacturers agree with the need to act, although they would rather take action via the standardisation process, without changes to the health and safety requirements of the MD (with some exceptions, such as the standalone software that fulfils a safety function, on which they agree it should be considered as a safety component). Manufacturers would also mostly prefer that the list of high-risk machinery remains unchanged, and that the obligation of third-party involvement in the conformity assesment remains non-mandatory. However, option 3 allows digital formats for the manual of instructions and the declaration of conformity, both widely requested by industry.

All stakeholder groups support the alignment to the NLF and the conversion of the MD into a regulation.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

For manufacturers: Savings of EUR 5 000 - EUR 10 000 per instance for clarifications of differences in interpretation between Member States; a reduction in printing costs of up to EUR 16.6 billion (EUR 201 000 per company) for digital documentation; simplification thanks to the MD coming under the same NLF framework as other pieces of product-safety legislation; cost savings thanks to fewer clarification procedures due to no transposition amounting to EUR 100 - EUR 500 per instance; better functioning of the single market; a more level playing field thanks to better legal certainty; and increased competitiveness.

For users (workers and consumers): Less non-compliant machinery on the market; increased safety thanks to clarifications; increased safety for workers and consumers; better protection of user's health and safety following the removal of internal checks for the conformity asessment of high-risk machinery; increased readability of non-paper instructions which will be better adapted for the blind and partially sighted; and access to ICSMS (the communication system used by Member States to assist in pan-European market surveillance).

For Member States: Greater legal clarity; access to ICSMS; saving on transposition costs.

For notified bodies: Decreased storage costs for manuals; benefits through equal interpretation across Member States.

For European standardisation organisations: Benefits expected from the equal interpretation of the regulation.

For society: Reduced social costs for sick leave and occupational injuries (e.g. savings for vibration-related sick-leave of EUR 15 million a year).

What are the costs of the preferred option (if any, otherwise main ones)?

For manufacturers: One-off costs for compliance and adaptation to changes on requirements; costs for third party involvement for the conformity assessment of high-risk machines EUR 202 million one-off overall; costs for purchasing, setting up and maintaining a server to allow the management of digital instruction and and declaration of conformity: one-off cost of EUR 29 million (EUR 1 000 per company), annual costs of EUR 48 million (EUR 3 000 per company).

For users (workers and consumers): Costs of changes to manufacturers could be pushed down the value chain to consumers; EUR 0.4 printing costs per manual in average if user decides to print the digital manual in one language after the purchase of the machinery.

For Member States: Costs of adapting to changes; one-off costs for adaptation to changes expected.

For notified bodies: An increase in turnover of EUR 202 million for the product portfolio of 10% of machinery under Annex IV currently assessed through internal checks; one-off costs for adaptation to changes expected.

For European standardisation organisations: Drafting and revision of new harmonised standards to provide presumption of conformity to the new and revised requirements.

How will businesses, SMEs and micro-enterprises be affected?

In the machinery sector, 98% of companies are SMEs. Legal certainty will particularly favour SMEs since they have fewer resources to assess and interpret the legal text. In addition, legal certainty on the safety requirements will result in clearer harmonised standards, which will also be beneficial for SMEs that rely on harmonised standards to comply with the safety requirements. Standardisation on emerging technologies happens in alignment with – and with reciprocal feedback from – the ISO/IEC (International Organization for Standardization /International Electrotechnical Commission) so that competitiveness within the EU and globally is maximised and exports are facilitated (key area for the EU machinery sector, which exports 51% of its production to countries outside the EU, and exports are also critically important for SMEs).

Manufacturers of Annex IV high-risk machines are often SMEs. However, it is not expected they face high costs increases because they often use third party involvement already for several reasons: (i) a lack of means (e.g. they do not have laboratories/expertise); (ii) as a guarantee of quality; and (iii) to improve brand recognition.

The following burden-reduction measures will favour SMEs: - cost savings for manufacturers by allowing digital instructions and digital declarations of conformity; - alignment to the NLF means a better functioning of the legislation and its enforcement, but also less burden for manufacturers dealing with several product-safety acts applying to their products; - complementarity between legal texts on AI and machinery, by which the AI regulation, for those AI systems covered by the MD, foresees that the conformity assessment is done only once, under the MD.
Will there be significant impacts on national budgets and administrations?
Member States will face some adaptation costs to make these changes. However, they will largely benefit from better legal clarity and alignment to the NLF, which will facilitate their market-surveillance tasks. Greater safety and less non-compliant machinery will reduce the need for intervention in the market. EU countries will benefit from reduced social costs for sick leave and occupational injuries.
Will there be other significant impacts?
A significant evironmental benefit for society will come from reduced use of paper to print instruction manuals and a corresponding decrease in carbon footprint.
D. Follow-up
When will the policy be reviewed?
By three years after the regulation becomes applicable and every four years thereafter, the Commission will submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council.