BRIEFING

Initial Appraisal of a European Commission Impact Assessment

European Parliament

Revising the Machinery Directive

Impact assessment (SWD(2021)82, SWD(2021)83 (summary)) accompanying a Commission proposal for a regulation of the European Parliament and of the Council on machinery products, COM(2021)202.

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's impact assessment (IA) accompanying the above-mentioned proposal, submitted on 21 April 2021 and referred to the European Parliament's Committee on the Internal Market and Consumer Protection (IMCO). This initiative, included in the Commission's 2020 and 2021 work programmes, reviews the existing Directive on Machinery 2006/42/EC (the 'Machinery Directive', the MD), which provides a regulatory framework (e.g. health and safety requirements, conformity assessment procedures) for placing machinery on the internal market. The revision, which takes the form of a proposal for a regulation, aims to take account of the impacts of new technologies, improve legal clarity of the current provisions, reduce certain costs for companies and ensure better coherence with the EU legislative framework for products. As part of a wider package on artificial intelligence (AI), it would also be coherent with the Commission's AI regulation proposal (e.g. AI systems embedded in a machinery).[1]

Problem definition

The REFIT evaluation of the MD (2018),[2] which was carried out in line with the 'evaluate first' principle, found that the MD has been an important piece of legislation for ensuring the safety of products and a level playing field in the machinery market. The evaluation also pointed out a number of gaps that should be addressed, such as risks concerning emerging technologies, the need for legal clarification of the current MD and simplification of the documentation (paper vs digital formats). In addition, the evaluation drew attention to the need to ensure better coherence with the existing product-safety legislation, improve enforcement of the legislation through aligning the MD to the new legislative framework (NLF), and to convert the MD into a regulation to reduce transposition costs. The IA also refers to the Commission report on the safety and liability implications of AI, the internet of things and robotics. This report, which analysed risks and impacts of new technologies on the product-safety legislation, concluded that new digital technologies pose new challenges to product-safety and liability, and that the current product-safety legislation, including the MD, contains gaps that need to be addressed. However, the IA does not explain the findings of this report in greater detail (IA, pp. 3-4, 51).

The IA has identified **six problems**:

P1) **'The MD does not sufficiently cover new risks originating from emerging technologies'**, which could have negative effects on the safety and level playing field. The IA also notes that accidents might undermine trust in new technologies. The IA mentions the need to better address the risks related to 'moving parts' (accidents in human-robot collaboration), cyber-safety aspects in the connected machinery, and software updates after the placing on the market of the machinery product, which may change its functionality. It also raises concerns on the lack of requirements on control mechanisms in terms of machines with learning capabilities (behaviour predictability), and the lack of requirements for autonomous (with no driver) machines (IA, pp. 11-14).

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P2) **'Legal uncertainty due to a lack of clarity on the scope and definitions and possible safety gaps in traditional technologies'**. According to the IA, the scope would need to be clarified in the interplay between the MD and the low-voltage directive (LVD) 2014/35/EU and the radio equipment directive (RED) 2014/53/EU (e.g. home-appliance products using radio equipment), as well as between the MD and EU type-approval legislation in relation to certain means of transport (e.g. multipurpose vehicles). Clearer definitions and criteria would be useful for 'partly completed machinery' (PCM) and 'substantial modification' of machinery requiring a new CE marking, in order to avoid safety issues and unequal terms for manufacturers. As for the traditional technologies, the IA has identified gaps, for example in terms of insufficient safety requirements on 'ride-on' mobile machinery, and the need to address emissions of hazardous substances from machinery in order to protect workers (IA, pp. 15-17).

P3) **'Insufficient provisions for high-risk machines'**. The IA finds that the list of high-risk machines needs updating (e.g. adding machinery embedding AI systems which fulfil a safety function), and that high-risk machines should systematically apply a third-party conformity assessment procedure, as it would better ensure safety and quality of machinery than internal checks. (IA, p. 18)

P4) **'Monetary and environmental costs due to extensive paper-based documentation'**. The documentation requirements are specified in the MD. The IA considers that this should be re-assessed, given the costs to economic operators and negative environmental effects. (IA, pp. 18-19)

P5) **'Inconsistencies with other pieces of Union product-safety legislation'**. The MD is not aligned to the 'new legislative framework' (NLF), which causes inconsistencies with other pieces of Union product legislation, and differences in the information provided in the conformity declaration, for example. The IA also refers to the issues of the 'lack of appropriate enforcement' of the MD (identified in the REFIT evaluation), and to the burdensome procedure concerning safeguard clauses (IA, pp. 19-20).

P6) **'Divergences in interpretation due to transposition'**. According to the IA, different interpretations by Member States may cause additional costs and obstacles in the internal market, and the IA notes also delays in transposition of the MD (IA, p. 20).

The **problem drivers** have been defined for each problem: i) 'emerging new technologies that create risks' (P1); ii) 'acceleration of market uptake of those technologies' (P1); iii) 'lack of standardised technical solutions' (P1); iv) 'areas of overlap in the scope of different pieces of product-safety legislation' (P2); v) 'lack of clarity in some definitions used in the MD' (P2); vi) 'risks linked to traditional technologies could be better addressed' (P2); vii) 'conformity procedures based on internal checks are allowed also for high-risk machines' (P3); viii) 'new types of high-risk machines have appeared on the market' (P3); ix) 'no digital documentation allowed' (P4); x) 'extensive paper-based documentation' (P4); xi) 'existence of improved framework to which MD has not yet been aligned (NLF)' (P5); xii) 'lack of coherence with other pieces of product-safety legislation' (P5); xiii) 'differences in interpretation in national transposing legislation' (P6); and xiv) 'differences in entry-into-force dates in each Member State' (P6), (IA, pp. 11-21).

The problem definition is based on the study on the revision of the MD supporting the IA, the REFIT evaluation, stakeholder consultations and other sources, such as reports, studies and analyses concerning the machinery sector. The problems are described together with the problem drivers, not separately, and the description is at times quite limited. It can be observed that some identified problems (in particular P5 and P6) appear to be similar to their problem drivers (xi, xii, xiii, xiv). The IA provides quantified descriptions of the machinery sector in Europe and of the growth rates and market shares of new technologies and various machinery segments. However, the IA presents only a few quantified estimates of the scale of the problems in terms of printing costs of user manuals (1-4 % of companies' turnover, annual recurrent costs of €6.63 billion-€26.5 billion), accidents in the agriculture sector in France due to contact between machines and overhead power lines (eight serious accidents in 2019), and a number of employees exposed to vibration-related injuries (portable hand-held and hand-guided machinery) in Sweden every year (400 000 per year;

extrapolated to the EU estimate of around 20 million employees exposed). The analysis would have benefited if the scale and possible consequences of all the problems had been explained further, to understand how big the problems are in relation to accidents, software updates, risks of machine-learning (ML), autonomous machines, and high-risk machines, for instance. The IA explains in a rather general manner that unless the identified risks and problems are not addressed, there could be consequences such as safety issues, distortion of competition among manufactures causing burden in particular for SMEs, and undermining trust in emerging technologies resulting from possible accidents. However, the IA does not really discuss these consequences in greater detail or illustrate them with concrete examples or estimates (IA, pp. 11-22, 42).

Subsidiarity/proportionality

The legal basis for the proposal is Article 114 of the Treaty on the Functioning of the European Union (TFEU). The IA and the annexed subsidiarity grid provide convincing justification for EU action. This initiative would address the identified gaps and issues of the existing MD, which has played a key role in ensuring the product-safety for users and the free movement of machines in the internal market. In the absence of EU action, Member States might issue their own safety requirements which could lead to a suboptimal level of safety, create barriers to trade, hinder innovation, and raise compliance costs for manufacturers. According to the IA, proportionality would be taken into account as the initiative would be technology neutral (allowing innovation by not imposing any specific technology), and the revision would be targeted. The form of a regulation would minimise differing interpretations, and avoid transposition delays and costs. However, proportionality is not used as a key criterion in the comparison of options, which would be required in the Better Regulation Guidelines (see also Toolbox, Tool#5) (IA, pp. 23-24, 68-71, 103-108). The deadline for national parliaments' subsidiarity check is 13 September 2021. No reasoned opinions had been submitted at the time of writing.

Objectives of the initiative

The IA identifies two **general objectives**. The first is to ensure 'a high level of safety and protection for users of machinery and other people exposed to it, and build a high level of trust in innovative digital technologies for consumers and users'. The second objective aims at 'the good functioning of the single market, including the digital single market' and to 'create a level playing field for economic operators and preserve the competitiveness of the machinery sector in global digital markets'. The IA defines six **specific objectives**, which are derived directly from the problems: SO1) 'cover new risks related to emerging digital technologies'; SO2) 'ensure coherent interpretation of the scope and definitions and improve safety for traditional technologies'; SO3) 'reassess machines considered as 'high risk' and reassess related conformity procedures'; SO4) 'reduce paper-based requirements for documentation'; SO5) 'ensure coherence with other product-safety legislation'; and SO6) 'avoid divergences in interpretation derived from transposition'. According to the Better Regulation Guidelines, the IA should present operational objectives, which are defined in terms of the deliverables of specific policy actions, after the selection of the preferred option (see also Tool #16). However, the operational objectives are not presented in the monitoring and evaluating plans, which link the indicators to the implementation and enforcement of the new provisions. In addition, objectives should be specific, measurable, achievable, relevant and time-bound (SMART criteria), however the formulation of the objectives is not time-bound, and could have been more measurable.

Range of options considered

The IA presents three policy options in addition to the baseline scenario. The IA also explains the reasons for discarding another two options, one of which would have completely overhauled the MD and the other, which would have repealed it (IA, p. 35).

Baseline: No action.

Option 1 (Self-regulation by industry and changes to the Guide to application of the MD)[3] would be a 'soft law' option as it would not introduce changes to the legal text of the current MD. New risks from emerging technologies (SO1) (e.g. human-robot collaboration, cyber security, machine learning) and certain risks from traditional technologies (SO2) (e.g. hazardous substances, overhead power lines, vibration peaks) would be dealt with through a Commission standardisation request process within the existing MD legal provisions. This option would revise the Guide ('with a push for consensus') and provide clarifications in order to tackle other identified issues (SO2-SO6) in relation to the scope and definitions (e.g. PCM, substantial modification, interplay in relation to LVD and RED), high-risk machines (software and logic units ensuring safety functions), paper-documents (digital format of instructions and conformity declarations allowed). Option 1 does not propose changes to the conformity-assessment procedures (SO3). In relation to SO6, Option 1 also proposes dedicated sessions of the Machinery Expert Group to deal with divergent interpretations in the Member States (IA, pp. 26-43).

Option 2 (Burden minimisation) proposes the same measure (standardisation) as Option 1 to address the new risks from emerging technologies (SO1) and risks from traditional technologies (SO2). In relation to SO2, this option would provide legal certainty by clarifying the scope and definitions in the legal text (e.g. PCM, substantial modification, interplay in relation to LVD and RED). In Option 2, the legal text would be revised to allow the adoption of delegated acts for reviewing the list of high-risk machines (SO3). As in Option 1, there would be no changes to the conformity-assessment procedures (SO3). Option 2 would adapt the legal text to allow digital format of instructions and conformity declarations (SO4). Option 2 would fully align the legal text with the NLF (SO5), and would convert the MD into a regulation (SO6), (IA, pp. 26-34, 43-50).

Option 3 (Burden minimisation and enhanced safety) (preferred option) proposes clarifications and targeted new safety provisions in the MD, as well as standardisation in relation to new risks of emerging technologies (SO1) and certain risks of traditional technologies (SO2). As for the emerging technologies, new requirements (Annex I) would concern e.g. human-robot collaboration, cybersecurity, ML test procedures. Furthermore, stand-alone software with safety functions would be included in the list of safety components (Annex V). New provisions would address risks of traditional technologies concerning e.g. hazardous substances, overhead power lines, vibration peaks (SO2) (Annex I). Option 3 includes the same measures for the clarification of the scope and definitions (SO2) as Option 2. In relation to SO3, Option 3 would use delegated acts for reviewing the list of high-risk machines and add two new items in Annex IV concerning 'software to ensure safety functions including AI systems' and 'machinery embedding AI systems ensuring safety functions'. Option 3 would also make the involvement of a third-party mandatory in the conformity-assessment procedure and would repeal the internal check options (Annex IV). This option would address SO4, SO5 and SO6 in the same way as Option 2 (IA, pp. 26-34, 50-67).

As required in the Better Regulation Guidelines, the IA presents a sufficiently broad range of policy options, including also one non-legislative option. Overall, the IA provides a good description of the proposed measures in the options, but could have explained the process of revising the Guide in more detail. Stakeholders' views are presented on measures – not on the policy options – although not systematically on all of them. It appears that stakeholders are in favour of the measures aiming at improving coherence and legal clarity, whilst their views seem to diverge more in relation to other measures, for instance concerning requirements tackling risks of emerging technologies (IA pp. 53, 64).

Assessment of impacts

The IA assesses the main economic, social and environmental impacts of the policy options. The assessment is mostly qualitative and quantification has been made 'whenever possible'. The impacts – costs and benefits – have been analysed for measures of each option, in relation to each specific objective (SO1-SO6), and the IA also presents overall effects of each policy option. In terms of **economic** impacts (partially quantified), the proposed measures would provide savings for

national authorities (transposition) and manufacturers (e.g. improved clarity, reduction of costs of paper-documents), and would improve manufacturers' competitiveness. There would be costs relating to familiarisation with changes made to the MD for manufacturers, national authorities, and notified bodies. Some measures concerning conformity assessment and maintaining the database for e-manuals would entail costs for manufacturers, and reviewing standards would mean additional work for standardisers. The IA estimates that there might be costs for users in the form of higher prices if costs are shifted to prices, while on the other hand users might benefit from access to innovative machinery in the market. As regards **social** impacts (partially quantified), the IA expects benefits for users in improved product safety and reduced numbers of non-compliant products on the market. On the other hand, the IA identifies both advantages (e.g. savings) and disadvantages of e-manuals (e.g. lack of access in certain environments). Expected fewer accidents would decrease health costs for national authorities. The assessment of **environmental** impacts (not quantified) is limited to the expected decrease in paper documentation, which would bring positive impacts due to the decrease in paper consumption and carbon footprint. The IA also very briefly mentions that clarification of the concept of 'a substantial modification' of machinery products would promote the circular economy, but does not discuss this in greater detail (IA, pp. 6-7, 35-67).

The policy options were compared against the defined objectives and the Better Regulation criteria of effectiveness, efficiency, and coherence. As regards **effectiveness**, the IA finds Option 2 and Option 3 more effective than Option 1, because they would for example provide revision of the legal text in terms of the scope and definitions, allow the revision of the list of high-risk machines through the adoption of delegated acts (instead of a full legislative process as it is the case currently), digital documentation, and full alignment to the NLF (SO5), whereas Option 1 would offer non-binding measures. The IA considers Option 3 more effective than Option 2, as Option 3 would introduce new provisions in relation to new risks of emerging technologies (SO1). It would also update the list of high-risk machines in the legal text (Annex IV) and oblige third-party involvement in the conformity assessment of high-risk machines (SO3). The comparison of options against **efficiency** is somewhat confusing, as the IA does not really present a clear analysis on how options score in terms of efficiency – contrary to effectiveness and coherence – regarding which the scoring has been done. The IA presents a comparison table of options against the efficiency criterion, which is vague, and refers to another table, which provides quantified estimates of impacts on stakeholder groups (pp. 67, 69). The IA finds Option 3 best in terms of **coherence**, as it would not only clarify the borderline with the LVD and RED and align the MD to the NLF (as in Option 2), but it would also ensure coherence with the future AI regulation (high-risk machines with the AI dimension) and the Cybersecurity Act. (IA, pp. 68-72) Even though the IA does not compare the policy options against the criterion of **proportionality**, it is discussed in the context of the preferred option. The IA points out that proportionality is ensured, as the revised 'safety requirements are targeted' and concern only specific machinery types, and the MD is technologically neutral (allowing various technological solutions and innovation for manufacturers) (IA, p. 71). In terms of presentation, the comparison of options is presented only by means of tables, which is not a very reader-friendly solution.

The IA provides quantified estimates of the expected direct benefits of the preferred option, for example reduced costs of work-related injuries (e.g. sick leave, early retirement) of €15 million per year, and savings from decreased printing costs of €16.6 billion (€201 000 per company). The IA also presents costs, which are partially quantified, such as increased costs for businesses for removal of internal checks in conformity assessment (€202 million per year/on average, €2 467 per company, up to €25 000 or more for certain types of machinery) and one-off costs related to digital documentation (€29 million/€1 960 per company) and recurrent annual costs (€48 million/€3 264 per company). No quantified estimates are presented for the compliance and adaptation costs relating to SO1, SO2, SO5 and SO6 (IA, pp. 89-90). It is to be noted that the IA provides quantified cost estimates for 'small' and large companies in terms of digital documentation and not for the other costs. No further differentiation by size of companies has been made to specify estimated costs.

SMEs/Competitiveness

The IA identifies that the machinery sector is 'one of the major sectors of the EU's manufacturing industry,' of which small and medium-sized enterprises (SMEs) are the 'main driving force' (IA, p. 7). SMEs represent 98 % of the manufacturers active in the market (81 024 SMEs and 1 703 large companies). According to the IA, an SME test has been carried out (see the Better Regulation Toolbox, Tool#22), the results of which are reported in a dedicated annex (IA, pp. 95-96). The IA mentions that SMEs have been 'extensively' consulted, but this could have been clarified and explained in more detail. In the description of the SME Test, the IA refers to the 'consultation with SME representatives', although from the IA it would seem that a dedicated consultation of SMEs has not been conducted. It would rather appear that the IA informs of the responses of the SMEs that participated in the public consultation. In addition, a question of representativeness of the reported views arises, as from the SME Test description, the number of replies to various questions range from 5 to 119, and the number of replies of 'no opinion' range from around 40 % to 54 %. The IA does not specify who the referred SME representatives were and which type of SMEs they represented (micro-/small/medium-sized businesses). As for the SMEs' views, there seemed to be wide support for aligning the MD with the NLF and conversion of the MD into a regulation, while on other issues, views were more divergent. Regarding the preferred option, the IA considers that the revision would improve the level playing field and the industry's competitiveness. In particular, the greater legal clarity would benefit SMEs, due to their access to fewer resources for legal advice, and savings are also expected, especially from the digital documentation. According to the IA, the preferred option would entail proportionate costs for manufacturers as the adaptation costs to new requirements would be low and targeted to certain machine types, and the revised conformity assessment procedure would not add significant costs for the manufacturers. The IA points out that SMEs 'often prefer' third-party assessment due to a lack of means (expertise) and as a guarantee of quality, and that half of the conformity assessment is already performed with third-party involvement for Annex IV machines (IA, pp. 55-65). Overall, it appears that the SME Test has not been fully conducted and it would have benefited the description of the SME Test, had it derived more information from the IA's supporting study, which provides more detailed information, for example of the respondents in the consultations (e.g. a breakdown by company size).

Simplification and other regulatory implications

This initiative is part of the Commission's regulatory fitness and performance programme (REFIT initiative). In the REFIT section, which is limited to a short presentation in a table, the IA presents estimates of cost savings of the preferred option (mostly quantified). The REFIT cost savings would result for example from decreased printing costs and reduction of occupational injuries. The IA explains how the MD relates to relevant existing EU legislation. The initiative would align the MD to the NLF as well as reinforce its coherence with the LVD and the RED. According to the IA, it would also be 'future-proof', as it would be coherent with the proposed regulation on artificial intelligence, and the Cybersecurity Act (Regulation (EU) 2019/881). The IA mentions that the initiative would provide simplification benefits in the regulatory environment by converting the MD into a regulation, aligning it to the NLF, and allowing digital documentation (IA, pp. 5-7, 26, 51-53, 72).

Monitoring and evaluation

The IA describes the monitoring plan with indicators and explains the data sources. The indicators, which appear relevant, are linked to the implementation and enforcement stages of the new provisions – not to the defined objectives – and the units of measurement for assessing their effectiveness are also presented. The Member States would have new reporting obligations in relation to high-risk machines, in order to gather statistics on accidents caused by machinery. The Commission would provide an evaluation report and a review report by three years after the entry into force of the new machinery regulation and every four years thereafter (IA, pp. 72-74).

Stakeholder consultation

In accordance with the Better Regulation Guidelines, the IA summarises the stakeholder consultation activities, which consist of a public consultation, interviews, and an online survey, in a separate annex (IA, pp. 79-86). The IA stresses that the aim of these consultations was to 'assess the potential areas of revision and the impacts of the suggested policy options on different stakeholder groups'. The IA provides a list of the stakeholder groups for all consultation activities. The IA explains that views of 98 stakeholders were gathered in **interviews**, of which 44 represented companies (no differentiation between SMEs and large companies). The **public consultation** was carried out from 7 June to 30 August 2019, meeting the 12-week requirement of the Better Regulation Guidelines. By the deadline, 523 responses were received, of which a majority came from companies (61 % were large companies). The targeted **online survey** – organised in November 2019 (no dates mentioned) – was due to fill some 'information gaps', but does not explain them. It collected 24 responses, of which 22 were from companies/manufacturers (share of SMEs/large companies not mentioned), one notified body and one expert on emerging technologies. The IA presents the views of stakeholder groups in relation to specific objectives, not to policy options. It appears that the views diverge on many issues (SO1-4), but in terms of SO5-SO6, aligning the MD to the NLF, and converting the MD into a regulation, have wide support among stakeholders. In the consultation summary annex, the IA does not report on the inception impact assessment, which gathered 115 responses between 14 January and 11 February 2019. Overall, the summary of the stakeholder consultations would have been more informative if it had made more use of the information provided in the IA's supporting study.

Supporting data and analytical methods used

The 2018 evaluation of the MD, the dedicated supporting study (conducted by Valdani Vicari & Associati, Deloitte and The Vienna Institute for International Economic Studies, Ecorys), stakeholder consultations, and other studies and reports in this policy field have fed in the preparation of the IA. The IA mentions also the contributions of the Machinery Working Group in the Council of the EU, and the European Social and Economic Committee (Information Report). The data sources are duly referenced and linked. The analytical methods used in the IA are explained in a dedicated annex, for example a multi-criteria analysis was used in the assessment of data, and a triangulation method (cross-checking) for the verification of the consistency of the findings. The annex also informs of the calculation methodology of impacts, and openly explains quantification issues due to data limitations. The IA notes that in emerging technologies, accident data is not available; consumers' incidents are not registered, and in terms of accidents at work, the reporting of causes and circumstances is not compulsory and the availability and reliability of this data is problematic. This gap has been mitigated by information from the Member States (IA, pp. 77-78, 91-94).

Follow-up to the opinion of the Commission Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) gave a positive opinion with reservations on a draft version of the IA report on 3 February 2021. The RSB pointed out a number of shortcomings in the draft, such as the need to provide sufficient evidence on the scope of the problems and clarify the content of the policy options, including their future-proofness and effects on standardisation. The RSB found that the comparison of options lacked clarity in terms of efficiency and effectiveness, and further descriptions were required in terms of a more transparent overview of the expected costs and benefits, SMEs and competitiveness, as well as simplification and solutions to data limitations. The IA provides a dedicated annex which explains how the RSB's recommendations have been addressed (IA, pp. 75-77). It appears that the RSB's concerns have only partially been taken into account. The IA still does not sufficiently illustrate the scale of the problems, and in the comparison of the options, especially in terms of efficiency, further clarification would have been needed. More detailed explanations would also have been useful in relation to the consultation of SMEs.

Coherence between the Commission's legislative proposal and the IA

The legislative proposal appears to follow the IA's preferred option, except that in terms of the evaluation and review, the proposal (article 51) would provide a longer timeframe (54 months after the entry into force instead of 36 months).

The IA analysis is based on various data sources, such as the REFIT evaluation, a dedicated supporting study, and stakeholder consultations. The assessment is mostly qualitative, but also presents quantified estimates. The IA openly explains the analytical methods and data limitations. The problem definition would have benefited if the scale of all problems had been illustrated further. The IA provides a sufficiently broad range of policy options, including one non-legislative option. In the comparison of options, the options are not considered against the criterion of proportionality, and the options are not scored in terms of efficiency. Overall, the comparison of options is presented by means of tables alone, and the efficiency aspect in particular would have benefited from further explanation. The descriptions of the stakeholder consultation and the reported SME Test are quite limited. It is, in fact, questionable whether the SME Test has been duly performed, as it would appear from the IA that a dedicated consultation of SMEs was not conducted. In general, stakeholders seem to support aligning the MD with the NLF and the conversion of the MD into a regulation, whereas in other issues, views appear to diverge more.

ENDNOTES

1 H. Dalli, The Artificial Intelligence Act, EPRS, European Parliament, 2021 (forthcoming).

2 I. Anglmayer, Machinery Directive: Revision of Directive 2006/42/EC, EPRS, European Parliament, 2021 (forthcoming).

3 The Guide is a non-binding informative document, regularly reviewed, in the machinery sector. A modification of the Guide requires consensus from all stakeholders. (IA, pp. 26, 37, 39)

This briefing, prepared for the Committee on the Internal Market and Consumer Protection (IMCO), analyses whether the principal criteria laid down in the Commission's own Better Regulation Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal.

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