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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	REGULATORY SCRUTINY BOARD OPINION Proposal for a Regulation of the European Parliament and of the Council on machinery products

Delegations will find attached document SEC(2021) 165 final.

Encl.: SEC(2021) 165 final

EUROPEAN COMMISSION

SEC(2021) 165

03.02.2021

REGULATORY SCRUTINY BOARD OPINION

Proposal for a Regulation of the European Parliament and of the Council on machinery products

{COM(2021) 202}
{SWD(2021) 82}
{SWD(2021) 83}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: **Impact assessment / Revision of the Machinery Directive**

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The Machinery Directive from 2006 defines essential health and safety requirements for machineries to be placed in the Single Market. Manufacturers can use harmonised standards to demonstrate that their products meet the legal requirements. The Directive ensures a high level of protection for workers and consumers. It also provides a level playing field in the internal market.

A recent evaluation identified the need to simplify and improve the Directive to adapt to developing market needs. A revision of the Directive would aim to address risks from new technologies, clarify concepts and definitions, allow digital formats for some documentation and align the Directive to the New Legislative Framework. It would also streamline implementation across Member States. The impact assessment examines ways to address these issues.

(B) Summary of findings

The Board notes the additional information provided in advance of the meeting.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The report does not provide sufficient evidence on the scope and magnitude of the problems (e.g. regarding safety requirements, legal instrument). It does not explain which are the most affected segments of the machinery sector.

(2) The report is not sufficiently transparent on the content and foreseen functioning of the policy options. It does not bring out clearly enough the key differences between the options, and where the main decisions lie for the political level. It does not sufficiently explore alternatives to deal with specific issues, such as on machine learning.

(3) The report lacks sufficient clarity on the role of the standardisation process and how future-proofness would be ensured, given the evolving safety risk and

This opinion concerns a draft impact assessment which may differ from the final version.

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technology landscape.

(4) The report does not compare the efficiency of options in a clear and informative manner. Trade offs between the options in terms of efficiency and effectiveness are not sufficiently explained.

(C) What to improve

(1) The report shuld be more specific on the scope and magnitude of the problems, for instance by differentiating between problems that affect specific segments of manufacturers or users, and problems that affect the overall sector. It should better substantiate the identified key issues and be transparent where there is a lack of, or only limited evidence available.

(2) The report should provide more information on divergent transposition and interpretations across Member States, and the related problems that might justify a change in legal instrument. It should explain to what extent the reliance on harmonised standards can help mitigate such divergences.

(3) The report should provide a comprehensive description of the content and functioning of the options in its options chapter. It should bring out more clearly their key differences, including by better justifying why certain provisions feature in certain policy options and not in others. It should explain if any alternative measures, or combinations thereof, were considered and, if so, why they were discarded. Where relevant, the report should further explore such alternative options. This should be the case for machine learning throughout the product life cycle, where alternative measures should be considered that might hamper innovation to a lesser extent while adequately ensuring safety.

(4) The report should clarify how some of the options would function. It should better explain why and for which types of machinery or new technologies the safety requirements or components (including in the annexes) would be changed under the preferred option. It should describe how this would affect current and future standardisation work. The report should better assess the future proofness of options, including the implications of dealing with upcoming new risks through standardisation.

(5) Overall, the quantitative analysis should be complemented by a qualitative explanation and assessment. The report should elaborate further the analysis of economic impacts, including on SMEs and competitiveness. It should present more clearly which provisions would contribute to simplifying the Machinery Directive.

(6) The comparison of the efficiency of options should be improved to provide a more transparent overview of the expected costs and benefits. This should also help to better explain trade-offs between options in terms of efficiency and effectiveness.

(7) The report should discuss possible solutions to solve data limitations in the future monitoring framework.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion **The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.** **If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.**	
Full title	Revision of Directive 2006/42/EC on machinery
Reference number	PLAN/2018/2979
Submitted to RSB on	18 November 2020
Date of RSB meeting	3 February 2021

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option (Policy Option 3)		
Description	**Amount**	**Comments**
Direct benefits		
Administrative cost reductions	Up to EUR 155,032,960,333 (EUR 1,885,151 per organisation) Up to EUR 127,583,851,984 (EUR 1,551,379 per organisation)	printing costs saved with digital manuals and a minimum safety related information in paper / printing costs saved with digital manuals and printed manuals on demand
Social benefits	EUR 1.5 billion yearly	Reduced social costs for sick leave and occupational injuries, medical examinations and early retirement, by reduced vibration peaks in handheld machines
Compliance cost reductions	EUR 5,000 to 10,000 per instance	These cost reductions for economic operators could be achieved through clarifications in scope and definitions resulting from lowering the costs related to resolving unclarities.
Increased legal certainty	Not quantifiable	A change of the requirements in terms of new technologies can lead to improved legal certainty and maintain a level playing field, particularly for manufacturers.
Indirect benefits		
Safety of products on the market	Reduction of non-compliant products (The removal of the internal checks option for conformity assessments of Annex IV machinery is expected to increase the effectiveness of the Directive to ensure the protection of health and safety of users.)	Machinery users would indirectly benefit from a clarification of the scope and definitions, as well as from new/revised targeted safety requirements through a reduction of non-compliant products on the market and increased safety. This benefit will be reinforced by the alignment of the MD to the NLF.

Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together). Stakeholder group main recipient of the benefit in the comment section is indicated. For reductions in regulatory costs, details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.) are provided.

II. Overview of costs – Preferred option (Policy Option 3)

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		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Specific Objective 1	Direct costs		Higher prices in the market if passed on by businesses	Compliance and adaptation to changes	Up to EUR 75,912 per firm for standalone software that fulfils a safety function	Compliance and adaptation to changes	
	Indirect costs						
Specific Objective 2	Direct costs			Compliance and adaptation to changes		Compliance and adaptation to changes	
	Indirect costs						
Specific Objective 3	Direct costs		Increased costs of products if additional costs are moved down the value chain	Familiarisation with new legal text (one-off).	If the internal checks procedure is removed: Increased costs for third parties conformity assessment /Annual EUR 202,895,485		
	Indirect costs						
Specific Objective 4	Direct costs		EUR 0.49 to 0.52 per manual if user decides to print part of the manual (number of manuals not identified)	EUR 29,013,919 (EUR 1,960 in average per firm)	EUR 48,317,057 (EUR 3,264 in average per firm)	Increased costs of adaptation to new procedure.	

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II. Overview of costs – Preferred option (Policy Option 3)							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
	Indirect costs						
Specific Objective 5 and 6	Direct costs			Some adaptation costs likely but expected to be marginal		Some adaptation costs likely but expected to be marginal	
	Indirect costs						

Estimates are provided with respect to the baseline. Costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified. If relevant and available, information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs) is provided.

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