



# **Impact Assessment Institute**

The Institute for Impact Assessment and Scientific Evaluation of Policy and Legislation

“Impartial Analysis for Policy Making”

**Study scrutinising the**

**Inception Impact Assessment on:**

the Revision of the Machinery Directive - Ares(2019)132242

## Main Findings

The Impact Assessment Institute has scrutinised the European Commission Inception Impact Assessment (IIA) on the revision of the Machinery Directive, with the following main findings:

- The IIA initially emphasises the challenges of digitalisation but subsequently refers to many drivers with equal emphasis on each. Clarification on the weighting of the drivers is necessary to guide ongoing policy development and better inform stakeholders.
- A number of assertions are made on economic impacts for which supporting evidence is not provided. Our analysis indicates that the preliminary assessment in the IIA contains inconsistencies and double-counting.
- In many cases expected impacts are presented but without explicit evidence and analysis. Several of the impacts would be more accurately described as intentions and should be presented as such.
- The potential for environmental impacts due to the intended effect of the initiative on efficiency has not been addressed and should be considered in future analysis.
- Due to the broad implications of the potential initiative on many industrial sectors, businesses and consumers, the IIA should have included a clear indication of the Commission services and resources to be employed in the Impact Assessment and legislative drafting.

In continuing work on the intended initiative, the above-mentioned clarifications are required in order to define for stakeholders and policy makers the weighting of the drivers behind it. Further, assessment of the evidence without preconceptions is essential.

## Visualisation

The following table provides a visual overview of the results of this report for each element of the evidence presented in the Impact Assessment, using an assessment from 1 to 7 to indicate the level of confidence (1 = highest, 7 = lowest confidence level).

Element	Assessment level & description (1...7)	Notes
Rhetoric	3 Several questions identified on analysis and/or evidence	The text is balanced but does not make clear what the main driver is for the initiative.
Assumptions	2 Minor questions identified on analysis and/or evidence	The background and assumptions are generally relevant and consistent.
Background data	2 Minor questions identified on analysis and/or evidence	There is little data relevant to the analysis performed at this stage in the process.
Analysis	4 Concerns identified with analysis and/or evidence	Assertions on economic impacts are made without supporting evidence. The analysis includes a number of inconsistencies and double-counting. Most of the projected impacts are intentions, which require full analysis in order to be verified as impacts.
Results	3 Several questions identified on analysis and/or evidence	The IIA generally refrains from prejudging the outcome of the full assessment, but the flaws in the analysis require correction to ensure valid results and conclusions.
Conclusion		

### Key to assessment levels

1	2	3	4	5	6	7
Correct analysis, fully evidenced	Minor questions identified on analysis and/or evidence	Several questions identified on analysis and/or evidence	Concerns identified with analysis and/or evidence	Substantial concerns identified with analysis and/or evidence	Serious concerns identified with analysis and/or evidence	Incorrect analysis / evidence absent

## 1. Introduction and General Comments

This study scrutinises the European Commission Inception Impact Assessment (IIA) on the Machinery Directive, published on 10<sup>th</sup> January 2019.

## 2. Section A. Context, Problem definition and Subsidiarity Check

The “Context” section highlights the emergence of digital technologies, notably artificial intelligence, as the primary driver for this initiative. It then proceeds to a more general level, quoting the overall objectives of the Machinery Directive and the findings of the REFIT evaluation. The “Problem” section includes the challenges of digitalisation as only the final one of four issues to be tackled. Similarly the evaluation<sup>1</sup> addresses a range of issues, of which the challenge of digitalisation is one.

A clarification is necessary in the ongoing work to enable a common understanding of the drivers for this initiative, in order to ensure consistent focus for the analysis. In particular this requires specification whether the focus on digitalisation in the introductory text correctly signals that digitalisation is the main driver or whether the problem definition and REFIT conclusions are more representative of the weighting of the different issues. This will provide correct guidance for internal resources and stakeholders for the ongoing developments.

### 2.1. Basis for EU intervention

The text covers the key elements of the treaty basis for the initiative and the need for EU level action with regard to the “essential requirements” for free movement.

This section refers to “technical solutions” elaborated as part of harmonised European Standards. However, the European Standardisation Organisations develop technical standards. Technical solutions are developed by the producers of the articles that meet those standards. This is a relevant distinction on which to ensure clarity in the ongoing work on this dossier.

## 3. Section B. Objectives and Policy options

This section begins by defining a general objective:

- to improve the functioning of the (digital) single market by ensuring the free movement of machinery within the EU and, at the same time, the highest level of safety

and two specific objectives:

- create a level playing-field for economic operators and preserve the competitiveness of the machinery sector in global digital markets; and
- establish a high level of trust in innovative digital technologies among consumers and users.

It does not explain how these are derived from the objectives of the Machinery Directive as quoted in the Context section:

---

<sup>1</sup> “Evaluation of the Machinery Directive”, SWD(2018)160, 7<sup>th</sup> May 2018, European Commission

- ensuring a high level of safety and protection for users of machinery and other people exposed to it;
- securing the free movement of machinery in the internal market.

There are clearly parallels between the two sets of objectives, but references to explain how the specific focus of the new objectives for this initiative have been derived from the well-established ones of the existing directive are necessary. A definition of “level playing field” in this context would also be necessary.

Assuming these objectives, and the further goals derived from them regarding provisions of legal clarity conducive to technological progress, the policy options appear to be comprehensive and balanced.

## 4. Section C. Preliminary Assessment of Expected Impacts

It is important when projecting impacts to differentiate between intended and expected effects of an initiative. This distinction is not always clear in this section, in particular for the economic impacts.

### 4.1. Likely economic impacts

The text states that Option 1 is not expected to have a major economic impact. However, in the “Problem” section the lack of coherence with the wider EU framework is quoted as generating administrative burden and additional costs to economic operators and authorities, implying an economic impact from the proposed alignment. This requires clarification.

The first bullet under Option 1 states that the effort in adapting documents would be compensated by the reduction in burden due to alignment with other EU legislation. No evidence is presented for this assertion, nor is the extent of the compensation stated – whether partially, fully or overcompensated. Additionally, this assessment should be part of the administrative burden section.

The second bullet refers to lower efficiency of this option by not addressing lack of legal clarity, but this is addressed as a positive impact under option 2 – i.e. it is double-counted.

For Option 2, the text states that the improvements in scope and definitions will increase legal clarity and ensure a level playing field. The link between the level playing field and economic benefits is not explained. It is clear that these outcomes are the intention of the alignment, but at this stage there is no evidence presented that they will result.

The economic benefits of allowing digital documentation appear to make qualitative sense. However, it is unclear why the “scope and definitions” issue has been assessed in only one sentence and combined with the digital documentation issues into a single point. These are two separate issues and as a major element of the intended initiative, the “scope and definitions” require more attention.

No evidence is provided for the statement that adapting health and safety requirements will make the sector more competitive. It may be reasonable to expect economic benefits from reduced absenteeism and accidents due to well-drafted legislation, for which there is ex-post evidence presented in the evaluation on the existing directive. However, to make this forward-

looking assessment, a full analysis of the potential future costs and benefits is required and at this early stage, before details have emerged, any conclusion is unsupported.

Raised trust of consumers and operators appears to be a reasonable expectation for an eventually well-designed adaptation, but the link to economic impacts is not presented and should not be assumed to be automatically understood.

Overall, the assessment of the economic impacts of option 2 depends strongly on the extent and nature of the changes to scope and definitions. It is more appropriate at this stage to refer to intentions rather than expectations or definite impacts.

The assessment of Option 3 projects negative impacts from not aligning to the new legislative framework, but these have already been counted as positive impacts under Option 2.

The assessment of Option 4 appears to be qualitatively reasonable. In further assessment the potential for added value through continuing to enable subsidiary differentiation by Member States within the context of a Directive should be fully assessed.

## 4.2. Likely social impacts

As a summary of the potential impacts of changes to the scope and definitions, this section appears to make a coherent qualitative case of the expectations.

## 4.3. Likely environmental impacts

The introductory section of the IIA refers to digital technologies and their potential to bring new degrees of efficiency and productivity. Therefore by implication this initiative is expected to have some impact on energy and greenhouse gas emissions, as well as possibly other environmental effects. This should be acknowledged and taken into account in the ongoing Impact Assessment work.

## 4.4. Likely impacts on fundamental rights

The impact on working conditions is a stated objective of the initiative and therefore the expectation of impacts on fundamental rights appears to be justified, if the initiative is effectively designed.

## 4.5. Likely impacts on simplification and/or administrative burden

Logically, the ability to provide digital documentation would be expected to reduce burdens on business by removing an obligation.

Before the details of improvements in the scope, definitions and health and safety requirements are determined, it cannot be said that they will probably reduce the costs to business. Well designed improvements with this objective in mind should achieve this goal. However, since the improvements may include new regulatory requirements and data requests, this could also potentially increase compliance effort and costs.

## 1. Section D: Evidence Base, Data Collection and Better Regulation Instruments

The section on Impact Assessment provides a clear general indication of how it is to be performed. It should additionally have provided an overview of the other resources and Commission services to be involved in the assessment.

The proposed evidence base appears to be relevant and complete.

The public and targeted consultations appear to be comprehensive. The synopsis of the consultations should refrain from overinterpreting the statistical results of the consultations. Without a robust weighting of responses nor any measure of the representativeness of voluntary responses, the weight of opinion, for example quoting majorities supporting a particular option, does not provide valid evidence.

### *Annex 1: Accompanying statement*

This report has been written according to the guiding principles of the Impact Assessment Institute: transparency, objectivity, legitimacy and credibility. It analyses the subject matter from a purely factual and scientific point of view, without any policy orientation. In respecting these principles it has been compiled following its written Study Procedures.

The analysis is open to review and criticism from all parties, including those whose work is scrutinised. Contacts with all relevant parties are recorded to ensure transparency and to guard against “lobbying” of the results.

By its nature the report has a critical characteristic, since it scrutinises the subject document with its main findings entailing the identification of errors, discrepancies and inconsistencies. In performing this work, the intention of the report is to be constructive in assisting the authors of the subject document and its background information as well as all relevant stakeholders in identifying the most robust evidence base for the policy objective in question. It should therefore be seen as a cooperative contribution to the policy making process.

This report is also to be considered as a call for additional data. Peer review is an essential step laid down in the procedures of the Impact Assessment Institute and this is manifested in the openness to further review and to identify new data. Even at publication of the final version, the report explicitly requests additional data where the readily available data was not sufficient to complete the analysis, and is open to newly arising data, information and analysis.