

## INCEPTION IMPACT ASSESSMENT

Inception impact assessments aim to inform the general public and stakeholders about the Commission's plans, so that they can provide feedback on the intended initiative and participate effectively in future consultation activities. In particular, the Commission invites them to provide views on its understanding of the problem and possible solutions, and to share any relevant information that they may have, including on possible impacts of the various options.

<b>TITLE OF THE INITIATIVE</b>	Revision of the Machinery Directive
<b>LEAD DG — RESPONSIBLE UNIT</b>	GROW.C3
<b>LIKELY TYPE OF INITIATIVE</b>	Legislative (Regulation)
<b>INDICATIVE PLANNING</b>	Adoption in Q2 2021
<b>ADDITIONAL INFORMATION</b>	<a href="http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery/">http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery/</a>

### A. Context, problem definition and subsidiarity check

#### Context

The EU has a competitive edge in world-leading industries such as manufacturing and robotics, producing more than a quarter of the world's industrial and professional service robots. With the emergence of new digital technologies such as Artificial Intelligence (AI) and the Internet of Things (IoT), the EU must remain competitive in a transformative global market. Emerging digital technologies are increasingly gaining a foothold not only in consumer applications but also at commercial/industrial level, where it can bring new degrees of efficiency and productivity.

The Commission's [Communication on Artificial intelligence for Europe](#) (adopted on 25 April 2018) shows how the EU is preparing an environment in which business and society can make the best use of AI. It refers to the [Machinery Directive 2006/42/EC](#) as the key piece of legislation on robots.

This initiative should be seen in the context of the fourth priority policy area under President Juncker's 'agenda for jobs, growth, fairness and democratic change', i.e. **a deeper and fairer internal market with a strengthened industrial base**.

The Machinery Directive has two overall objectives:

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

The products that it covers range from lawnmowers to 3D printers, from powered hand-tools to construction machinery, and from robots to complete automated industrial production lines. An additional objective, protecting the environment, is limited to the machinery used in pesticide applications.

This initiative addresses the issues identified in an evaluation of the Directive, which was carried out as part of the Commission's regulatory fitness and performance (REFIT) programme. The evaluation concluded (see [SWD \(2018\)160](#)) that the Directive is generally relevant, effective, efficient and coherent, and has EU added value, but that there was a need for specific improvements and simplification.

While the evaluation indicates that the Directive allows for technological developments in a digital era, given that it is underpinned by the 'new approach' principles which sets mandatory basic requirements, leaving the technical details to meet those requirements to standardisers, further analysis is needed as regards its effectiveness and fitness for purpose going forward, with respect to developments in digitalisation, such as IoT, AI and the new generation of autonomous robots.

#### Problem the initiative aims to tackle

Any revision of the Machinery Directive will take into account the need for greater legal clarity, simplification and adaptation to technical progress. More specifically, the problems the initiative aims to tackle are:

- **a lack of coherence with the wider EU framework and enforcement difficulties** – the fact that the Directive is not aligned with the 'new legislative framework' (see [Decision No 768/2008/EC](#)) generates

administrative burden and additional costs for economic operators, market surveillance authorities and EU institutions (e.g. the procedure for handling safeguard clauses, the form and content of documentation, etc.);

- **a lack of legal clarity in the scope and definitions** – experience from implementing the Directive indicates a lack of legal clarity in some of its provisions. In particular, the definition of ‘partly completed machinery’ gives rise to legal uncertainty and additional costs for operators and national authorities. Also, certain categories of products that are explicitly excluded from the scope are not defined in such a way as to ensure clear delimitation *vis-à-vis* other applicable legislation, e.g. the Low Voltage Directive;
- **administrative burden and additional costs for operators** due to requirements for paper documentation – the Directive is not clear as to whether the documentation accompanying products can be in digital formats; and
- **challenges posed by technical progress in digitalisation**, e.g. AI and IoT.

The Communication on AI referred to the Directive as the EU’s central safety framework for AI robots. The problems the initiative aims to tackle concern certain essential health and safety requirements that have been in force for over 10 years and relate to emerging (‘state of the art’) digital technologies such as AI, IoT and advanced autonomous robots. Consideration will be given to the autonomous behaviour of AI systems and robots and to cyber threats. Consistency with the Commission’s work strands related to AI, such as deliverables of the [European AI Alliance](#), will be ensured. Cybersecurity requirements may be addressed by specific revised legislation on machinery or through cross-cutting measures. The interaction of any new solution on cybersecurity with the existing legal framework, in particular the [Radio Equipment Directive](#), will be assessed.

This initiative aims to examine the possibility of **converting the Directive into a Regulation**. A Regulation would be directly applicable in the Member States and so simplify matters for stakeholders and national administrations.

#### **Basis for EU intervention (legal basis and subsidiarity check)**

The Machinery Directive is a total harmonisation Directive based on Article 114 TFEU (ex-Article 95 TEC) and the ‘new approach’ to technical harmonisation and standards. Under the “new approach” principles, the EU legislation defines the “essential requirements” (in relation to the protection of health and safety and other aspects) which products must satisfy in order to benefit from the free movement of products across the Internal Market. However, the EU legislation does not prescribe the specific technical solutions to meet these essential requirements. The elaboration of such solutions is entrusted to the European Standardisation Organisations which develop harmonised European Standards. While compliance with these harmonised European Standards remains voluntary, it nevertheless gives rise to a presumption of conformity with the relevant essential requirements. Any changes to its 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. Objectives and policy options**

The **general objective** is 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.

The **specific objectives** are to:

- **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.**

The whole revision process is aimed at improving the legal clarity of some major concepts and definitions in the current text of the Directive. Also, alignment with the ‘new legislative framework’ will ensure coherence with the wide EU framework and improve enforcement of the legislation.

On the basis of the conclusions of the REFIT evaluation, this initiative aims to make the Directive conducive to technological progress in digitalisation. Together with the new mechanisms for enforcement and compliance provided for in the Commission’s [‘goods package’](#) proposal, it is expected to provide a clear and stable legal framework that contributes to the development of the (digital) single market. As a consequence, operators will be able to manage their activities more effectively and be more competitive in global markets.

In line with these objectives, the Commission is considering the following **policy options**, which are based on the findings from the evaluation:

- **option 0** — baseline scenario (no change);
- **option 1** – aligning the Directive with the ‘new legislative framework’, with no change to the substance of the current act (scope, definitions, essential health and safety requirements);
- **option 2** – aligning the Directive with the ‘new legislative framework’, with changes to:
  - its scope and definitions, e.g. adapting the list of excluded low-voltage products and improving the definition of ‘partly completed machinery’; and/or
  - the essential health and safety requirements, so as to:
    - allow digital documentation; and/or
    - explicitly address aspects relating to emerging digital technologies, e.g. AI, cybersecurity, IoT.
- **option 3** – adapt the Directive’s scope and definitions and/or essential health and safety requirements (as in option 2) without aligning it with the ‘new legislative framework’; and
- **option 4** (together with option 1, 2 or 3) — convert the Directive into a Regulation.

### C. Preliminary assessment of expected impacts

The expected impacts of all the options will be analysed in an impact assessment based on the findings of an impact assessment study by an external contractor.

#### Likely economic impacts

**Option 1** (alignment with the ‘new legislative framework’, with no change to the substance of the current act) is not expected to have a major economic impact, as changes to the legislation and requirements for operators would be basically formal in nature:

- the effort involved in adapting the relevant documents under the Directive (declaration of conformity, technical file, instructions, etc.) would be compensated by a reduction in the administrative burden thanks to the alignment with the other EU legislation potentially applicable to the products in question;
- since this option will not address the lack of legal clarity in the scope and definitions, nor relax the requirements for documentation by allowing digital formats, there might be a drawback effect on efficiency going forward; and
- adaptation to digitalisation might be left to market participants, through self-regulation. This is not expected to have a major impact, as there are no changes in the legislation. European harmonised standards could be leveraged to cope with changes in digitalisation. However, further analysis will indicate how this option would enhance the level playing-field and therefore have a positive [impact on the sectoral competitiveness](#) of EU mechanical engineering (especially [SMEs](#)) in a global digital market.

**Option 2** (alignment with the ‘new legislative framework’, with changes to the scope and definitions and/or the essential health and safety requirements, as regards documentation and/or the challenges posed by digitalisation) is expected to have positive impacts in the long term:

- improvements in the scope and definitions will increase legal clarity and ensure a level playing-field for manufacturers of machinery. Adapting the requirements for documentation by allowing digital formats (e.g. digitally displayed on the product or through access via internet or flash drives) is expected to reduce administrative burden for economic operators, with an additional positive impact on environmental costs, especially for products manufactured in series, where each product has to be accompanied by an instruction manual and declaration of conformity; and
- adapting the health and safety requirements in the light of the challenges posed by emerging digital technologies is expected to make the machinery sector more competitive and leverage the public’s and operators’ trust in emerging products such as autonomous AI robots and IoT. Key questions linked to the safety of AI systems, such as the transparency of algorithms, cybersecurity and human-robot coexistence, may be addressed more explicitly. This option is therefore expected to:
  - foster the competitiveness of the EU industry in a transformative digital global market; and
  - raise the level of consumers’ and operators’ trust in these technologies.

EU businesses and citizens could benefit from greater protection from cyber threats. Further analysis will be carried out on the feasibility of introducing new legal requirements to enforce ethical rules and principles, in

coherence with the work carried out by [the European AI Alliance](#).

**Option 3** (adapt the Directive's scope and definitions and/or essential health and safety requirements, as in option 2, without aligning it with the 'new legislative framework') will have positive economic impacts thanks to greater clarity in the Directive. However, its non-alignment with the 'new legislative framework' will impair coherence and enforcement.

**Option 4** (convert the Directive into a Regulation for option 1, 2 or 3) is expected to cut the costs relating to transposition and prevent delays that affected both national authorities and the Commission during the transposition of the current Directive.

#### **Likely social impacts**

Options 1 and 4 are unlikely to have any social impacts.

Options 2 and 3 are expected to provide significant improvements for consumers, users and operators of machinery by building trust in emerging digital technologies. At the same time, they will have a direct impact on the labour market, due to the need to upskill/reskill workers to operate new digital machinery and to tackle the increasing demand for digital skills in the sector. Allowing digital format for documentation may create user convenience, but may also have an impact on consumers who are not digitally literate. The latter may contribute to the 'digital divide'.

#### **Likely environmental impacts**

Options 1 and 4 are unlikely to have any environmental impacts.

Options 2 and 3 are expected to generate positive impacts for the environment by reducing or eliminating the production of paper documentation.

#### **Likely impacts on fundamental rights**

Options 1 and 4 are not expected to have any impact on fundamental rights.

Options 2 and 3 are expected to enhance fair and just working conditions as regards safety (Article 31 of the [Charter of Fundamental Rights of the European Union](#)) for workers dealing with AI robots and emerging digital systems. Extending the Directive's requirements to cybersecurity is also likely to help protect information-related rights, as enshrined in the Charter, particularly the right to the protection of personal data and private life.

#### **Likely impacts on simplification and/or administrative burden**

Options 2 and 3 would probably have benefits in terms of reducing unnecessary regulatory and administrative burdens in the sector. Allowing for digital product documentation is expected to have positive impacts for operators, in particular SMEs, which are proportionately more affected by the direct and indirect costs of legislation. Improvements in the scope, definitions and health and safety requirements will probably reduce the costs relating to businesses' (especially SMEs') efforts to design innovative, safe and cybersecure products.

A Regulation (option 4) would represent a common and directly applicable reference, unlike the different national legislative acts for different stages of transposing a Directive.

### **D. Evidence base, data collection and better regulation instruments**

#### **Impact assessment**

An [impact assessment](#) will be carried out on the basis of the findings of the evaluation of the Directive. The impact assessment report accompanying any Commission proposal for revised EU legislation on machinery will be supported by an impact assessment study, which will be carried out by an external contractor under the relevant Commission framework contract over a period of 13 months (January 2019 to February 2020).

#### **Evidence base and data collection**

In line with the general principles in the [Better Regulation Guidelines](#), in particular on the need for evidence-based impact assessment, the collected evidence and data would include:

- the staff working document on the evaluation of the Directive ([SWD\(2018\) 160](#));
- experiences, approaches and agreements from members of the various working parties for the Directive (committee working group, administrative cooperation group, notified bodies group);

- guidance documents drawn up in the framework of the working parties' activities;
- technical reports, position papers and other documents drawn up by relevant stakeholders; and
- data from internet-based open public consultations, targeted consultations and interviews.

### **Consultation of public and stakeholders**

The consultation strategy will involve gleaning views and reliable key information from the general public and relevant stakeholders. In particular, for the impact assessment, the consultation will collect feedback on the nature of the key problems, and the proposed options and their potential impacts.

The following specific consultation activities will be carried out:

- all interested stakeholders will be able to provide feedback on this inception impact assessment over a four-week period;
- a 12-week public consultation in all EU languages will be launched on the Commission's central public consultation webpage ([‘Contribute to law-making’](#)) to consult the public, operators, Member States and other interested parties on the main issues and possible solutions;
- targeted consultations will be carried out with the support of the consultants working on the impact assessment study, in particular addressing Member State authorities, notified bodies and Europe-wide stakeholder organisations; and
- regular consultations with stakeholders, experts, workers/users and other interested parties at EU level will be held through the committee working group, administrative cooperation group and notified bodies group.

In all these activities, particular consideration will be given to SMEs likely to be affected by the possible revision (ensuring that they have access to them through the internet) and the most representative European organisations.

The results of all the activities will be summarised in a synopsis report published on the consultation webpage.

### **Will an implementation plan be established?**

Yes. An [implementation plan](#) will help Member States to apply the new legislation consistently and effectively, in particular in the transition period. It will include specific information and communication activities, guidance documents and a public workshop.