

POSITION PAPER

Brussels, 8 February 2019

Orgalim's answer to the European Commission Inception Impact Assessment on the Revision of the Machinery Directive 2006/42/EC

Orgalim's industries represent a wide variety of sectors in the manufacturing industries, the vast majority of which are small and medium sized enterprises for whom the Machinery Directive is the core piece of legislation.

Both the recent publication of the Evaluation report on the Machinery Directive (MD) and the Communication on Artificial Intelligence (AI) respectively underline that the MD is fit for purpose and that the EU safety framework is robust enough to provide for machines embedding AI-driven functions. Nevertheless, both documents suggest some light adaptations to foster coherence with the EU legislative framework.

Consequently, **Orgalim does not favour Option 0** - the baseline scenario- as we acknowledge that further coherence is needed with the broader legal framework, mainly in relation with the New Legislative Framework (NLF) and especially with the provisions of Decision 768/2008.

Orgalim supports Option 1 which would align the Directive with the NLF without bringing any change to the substance of the current legislative act. Indeed, the MD is a new approach directive which performs well thanks to both the Essential and Health Safety Requirements (EHSRs) of Annex I and the approximately 800 harmonised standards which represent the State of the Art. The alignment to the NLF would help to reduce administrative burdens for our manufacturers who need to apply the Machinery Directive in combination with other EU legislation. It would also help national authorities to simplify their market surveillance activities and improve the effectiveness of their measures. Last but not least, it would significantly reduce the number of non-compliant products on the market.

Orgalim represents Europe's technology industries: companies that innovate at the crossroads of digital and physical technology. Our industries develop and manufacture the products, systems and services that enable a prosperous and sustainable future. Ranging from large globally active corporations to regionally anchored small and medium-sized enterprises, the companies we represent directly employ 11 million people across Europe and generate an annual turnover of around €2,000 billion. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

Orgalim does not support Option 2 which foresees the adaptation of the scope and the definitions of the Directive as well as the EHSRs in order to address the particular issues relating to emerging digital technologies. Thanks to the EHSRs and the around 800 harmonised standards which reflect the State of the Art, our industries have already been placing machines embedding new technologies on the market for several decades without any compromise to the safety of both users and consumers. Before placing machines on the market, our companies already need to carry out a conformity assessment procedure including the risk assessment to fulfill the EHSRs of Annex I and eliminate any potential risks. This is valid for all kinds of machines, whether or not they embed AI-driven functions, and ensures a high level of trust for all, especially for the users who are employees in many cases. We refer the Commission to [our position paper](#) on the issue of AI versus MD for a more detailed discussion.

The only sub-option in Option 2 Orgalim would support is allowing manufacturers to provide their documentation in a digital format. This specific sub-option can be integrated in the guide of interpretation to the MD without any modification to the legislation and would allow our manufacturers to reduce the administrative burden, to improve the use of the instructions to reflect the needs of digitalisation, and to remain competitive on the market.

Orgalim does not support Option 3 as it entails a modification of the scope (see Option 2) without aligning to the NLF, which we consider important (see Option 1).

Orgalim supports Option 4 of turning the Machinery Directive into a Regulation as this would allow a harmonised interpretation of the legal act in all Member States, avoid transposition problems in the Member States, and ultimately contribute to the completion of the internal market of goods.

Given the comments expressed above, **Orgalim recommends including an Option 5** in the Impact Assessment Study. This Option would incorporate the issues which help to foster the internal market, help our companies to be more competitive, and guarantee a stable legal framework for the continued placing of safe machines on market as they have done so far. This option 5 should include the following sub-options:

- The adaptation of the Machinery Directive 2006/42/EC to the New Legislative Framework
- The possibility for our companies to use digital documentation
- The turning of the Machinery Directive into a Regulation.

Note: Please note that our Swiss member organization SWISSMEM is – in line with the general Orgalim position – against any revision of the Machinery Directive. However, due to political reasons related to the ongoing interinstitutional framework agreement between Switzerland and the EU, SWISSMEM is further not prepared to support the 'option 5' presented in Orgalim's response to the inception impact assessment. We can provide you with further information should you require.

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