Policy Exchange on Machinery Regulation - Impact on our industries

THURSDAY 30 MARCH 2023, 10.00 – 11.30

Q&A

General Questions - Introduction

Please explain why the legislative instrument that is used this time is a "Regulation" instead of a "Directive"?

A Regulation is directly applicable in all Member States from a given date, while a Directive has to be transcribed into the national law of each Member State. As such, Orgalim welcomes the use of the Regulation which is a legal instrument that provides better harmonisation and legal stability.

Are we sure that the regulation will be published before July 2023?

Currently the official signing ceremony is foreseen in June and the publication in the Official Journal of the EU is foreseen in July 2023. The last formal steps are still being taken, however we do not foresee any delays to this timeline.

With relevance to the harmonisation procedure, would it be possible that a Member State requests more stringent requirements than other states?

(Answered by the European Commission)

No. The future Machinery Regulation is a total harmonisation legislation for the aspects it covers.

Have members of EU Commission been contacted by UK authorities to implement the new regulation in the UK as well?

(Answered by the European Commission)

No.

What about "substantial modification" due to other directives? Now, it is only covered for Machinery Regulation but it also has to be considered for EMC, RoHS, …

Substantial modification is already explained in the Blue Guide which provides horizontal guidance for the legislations covered by the New Legislative Framework (NLF) including EMC and RoHS. This concerns the characteristics of a substantial modification as well as the legal consequence, i.e. the obligation for CE marking. In accordance with these explanations, a decision can be made for each CE marking provision as to whether a product that was covered by one of these provisions when it was placed on the market is substantially modified when it is converted.

If a machine that was covered by the scope of the EU Machinery Regulation when it was placed on the market is substantially modified, this means that all CE marking requirements must then be met, as the CE marking obligation applies to the substantially modified machine.

"Importers" are defined as the person "who places a product within the scope of this Regulation from a third country on the Union market". What about persons that import for their own use? They are also not "manufacturers" or "distributors".

The legislation assumes that those who import for their "own use" are the consumers or end-users of the product. They are not considered as importer due to the lack of making the product available for the first time (=placing on the market) "in the course of a commercial activity". They are not considered manufacturers unless they integrate the product into another product or modify the product for further sale.

Questions related to third-party conformity assessment

Which 6 products categories will have a mandatory notified body conformity assessment?

The product categories listed in Annex I, Part A designated for conformity assessment with the involvement of a notified body are:

1. Removable mechanical transmission devices including their guards;

2. Guards for removable mechanical transmission devices;

3. Vehicle servicing lifts;

4. Portable cartridge-operated fixing and other impact machinery;

5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions;

6. Machinery embedding systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only to those systems.

Annex I, Part B machinery is subject to 3rd party involvement if the manufacturer has not applied a harmonised standard or if the harmonised standard applied does not cover all the risks presented by the machinery.

"Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment." What does this mean and how will it be regulated?

(Answered by European Accreditation)

It is an obligation for the notified bodies to take into account the specific interests and needs when setting the fees for conformity assessment. Recital 27 gives more explanation on this: *'In order to reduce the regulatory burden on SMEs, it is important that notified bodies **consider** adapting the fees for conformity assessment and reducing them proportionately to the specific interests and needs of SMEs'*. Notifying authorities should/can look into this when notifying the conformity assessment bodies or during the follow-up of notified bodies.

At EA level there is a FAQ under the Certification committee that mentions following:

A certification body does not have to charge all clients that are in the same condition the same fee. Offering discounts does not 'impede or inhibit' access by applicants, neither does it impose 'undue financial or other conditions'. The fees charged by a certification body are a purely commercial decision for the certification body and it is perfectly acceptable for a CB to charge different clients different fees, providing the certification process is applied equally to all clients. Certification bodies operate in a competitive environment. Most clients obtain multiple quotations for certification and cost will be one of the factors taken into account. Certification bodies need the flexibility to vary their fees in order to attract clients. There is no requirement in ISO/IEC 17065 for the CB to justify the reasons for the fees it charges or for applying a discount.

Digitalisation of Paper Documents

Are any subsidies planned to be available to support the process of digitalisation of paper documents?

The possibility to provide documents in digital format is voluntary. If a manufacturer decides to continue to provide the documentation in paper format it will still be acceptable, however, according to the

Commission's calculations providing instructions and conformity assessment documentation in digital format can account for considerable cost savings and is more environmentally sustainable. No subsidies are currently foreseen to support this transition.

Related to the requirement to deliver paper instructions to non-professional users: often the manufacturer doesn't know if the client is professional or non-professional. Does this mean that paper instructions would have to be delivered in these unknown cases?

The requirement concerning non-professional users only covers instructions that are essential for the safe start and use of the machinery product. The assumption is that such instructions can be delivered in a simplified instruction manual (1-2 pages) that is complimented by the full instruction manual in digital format. If the manufacturer doesn't know if the end user is a professional or non-professional, then the product can be considered as intended for professional use by the manufacturer. If the product is sold to non-professional end users, it is up to the distributor to request a simplified instruction manual in paper format from the manufacturer. According to the regulations, machines are also to be considered non-professional if it is reasonable to expect that they may reach consumers.

How does the European Commission ensure that the digital versions are accessible considering that there are areas where internet coverage is restricted or smartphone technology is not available for all the end users?

The possibility to provide documents in digital format is voluntary. Where the manufacturer decides to provide instructions in a digital format Article 7 (10) of the Regulation provides clear requirements to ensure that the instructions are easily retrievable, "*the manufacturer shall:*

(a) mark on the machinery or related product and on the packaging or in an accompanying document how to access the digital instructions;

(b) present them in a format that makes it possible for the user to print and download the instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machinery or related product. This also applies where the instructions are embedded in the software of the machinery or related product or provided on a data carrier;

(c) make them accessible online during the expected lifetime of the machinery or related product and not less than 10 years after the placing on the market of the machinery or related product."

Orgalim will propose further clarifications and case examples that can support this provision in the guide of interpretation.

Furthermore, the regulation provides the possibility to request paper documentation for the machinery from the manufacturer "at the time of purchase".

What is meant by "at the time of purchase"? Is it, when the payment is made for the machinery? When the contract is signed? Just before putting the signature on the contract? When drafting the contract? ...

The wording "at the time of purchase" is not further specified by the provisions on CE marking. In our opinion, this is not necessary. What is meant is the point in time at which the customer declares the purchase of the machinery. This may concern different aspects depending on how the machinery is to be made available. This can be, for example, the binding order. From the point of view of the provision, it is about the point in time when the manufacturer is aware of the customer's wish and can take it into account.

When we speak about digital instructions, do you expect that the corresponding horizontal standard 82079-1 will be harmonised?

82079 is a standard designed for electrical equipment, the majority of which are consumer products. For machinery there is already a harmonised standard, EN ISO 20607.

Would UNE be including in standards for the new regulations standards related to requirements for technical communications regarding instructions for use.

(Answered by UNE – Spanish Standardisation Organisation)

In this case UNE cannot unilaterally include specific requirements in the standards, the development of standards follows a process based on the work of the European committees that seek the consensus of all stakeholders, UNE can request the inclusion, propose new requirements and even raise national standards to European standards.

Questions related to technical requirements

With respect to the technical requirements for machinery does the new Machinery Regulation always build on the requirements of the existing Directive or are there any conflicting technical requirements that would then require changes rather than simply additions?

The changes to the technical requirements are additional, stricter requirements or new requirements. There are no new requirements that are in direct conflict with the old requirements.

How shall we handle new ESHR that are not technically possible to comply with for certain products? In particular ESHR 3.5.4 is technically not possible to comply with for mobile cranes.

Regarding ESHR 3.5.4: The question to be clarified is whether state of the art measures are available to meet this requirement. If no technical measures are available, the manufacturer must identify a residual risk and include a warning in the operating instructions or affix it to the machine.

(Answered by the European Commission)

We do not share this view but are happy to receive detailed information regarding possible issue for mobile cranes.

Will there be concrete and harmonised standards for cybersecurity risk assessment, e.g. EN IEC 62443-*?

A type B standard is planned for EHSR 1.1.9 that covers this requirement across machines and shows solutions that correspond to the state of the art.

How does the regulation impact autonomous agriculture machinery in practical terms?

If machines can be operated autonomously, the applicable EHSRs of Annex III of the new regulation must be fulfilled. A harmonised Type C standards or a Type B standard will need to be developed, which may affect a range of agricultural machinery, and provide solutions to build protective measures that correspond to the state of the art.

Common Specifications:

How does the EC envision the development of Common Specifications if necessary? How will the EC ensure that the process will be open, transparent, and consensus-based and will include all of the relevant technical subject-matter experts?

(Answered by the European Commission)

Any technical specifications, before they are adopted (will be adopted as implementing acts), will be discussed in the relevant expert group where stakeholders also participate; in addition the documents will be open to pubic consultation via the Better Regulation portal; as one of the recitals (40a of the provisional deal) states: *'With a view to establishing, in the most efficient way, common specifications that cover the essential health and safety requirements of this Regulation, the Commission should involve relevant stakeholders in the process'*.

Is there a current interpretation for how Art. 4a of the regulation should be read: "*Member States may lay down requirements to ensure that persons, including workers, are protected when installing or using machinery or related products, provided that such rules do not allow for modification of a machinery or related product in a way that is not compatible with this Regulation".*

(Answered by the European Commission)

The above provision provides some discretion to Member States, which concerns the installation, and also sets a proviso; if needed the revised MACHINERY Guide will include more details.

Questions related to standardisation activities:

Does the EC plan to implement a mechanism (e.g., a table, a statement/clause within Annex Z or a combination of measures) that would allow manufacturers intending to use harmonised standards to be informed on how to comply with the MR?

(Answered by the European Commission)

Harmonised Standards prepared in reply to a Commission request must have an 'Annex Z'.

What type of tools are CEN and CENELEC planning to use to keep the standardisation process transparent and to work together with the industry regarding the harmonised standards considering all those new EU standards?

(Answered by UNE – Spanish Standardisation Organisation)

The tools are known to all, use of the CEN DOCUMENTS electronic platform, joint work with the national standardisation bodies and all the sectors involved and the continuous supervision of the HAS consultants in the new evaluation process of future harmonised standards.

The EC will issue to CEN and CENELEC the Standardisation Request which will replace the current mandate for machinery M/396. In the Standardisation Request, the EC will explain what is required to be done and within which deadlines. The EC is currently preparing the draft Standardisation Request which will soon be shared with stakeholders. All the standardisation Technical Committees (TCs) will be invited to reply to the consultation. CEN-CENELEC Sector Forum on Machinery and CEN CENELEC Management Centre (CCMC) will continue to discuss the next actions that are expected and the corresponding practical steps with the EC. The TCs will be kept informed about new developments.

How will ISO standards harmonised under the Vienna agreement be handled? Will it be possible to transfer the current EN ISO standards to the new Machinery Regulation if the ESHR that these standards cover have not been amended and no new ESHR apply? If yes, what should be done on the standard side? (If the standard is not in line with the CEN guidance, put the standard in compliance to this guidance? e.g. add annex ZZ or ZA)

(Answered by UNE – Spanish Standardisation Organisation)

There is a clear intention of the European Commission (EC) to transfer all harmonised standards in support of the Machinery Directive to the list of harmonised standards cited in the Official Journal of the EU (OJEU) under Machinery Regulation. As a first step, the consolidated OJEU list of harmonised standards under the old Machinery Directive is expected to be published before the Machinery Regulation becomes mandatory.

This package is then intended to be also transferred into the OJEU list under the Machinery Regulation. New requirements will have to be included in C-standards reviewed according CEN Guide.

In the latest text of the Machinery Regulation, the correlation table in Annex XI does not include any details on which section of the Annex I (EHSR) of the MD 2006/42/EC is equivalent to which section of Annex III (ESHR) in the future Machinery Regulation? It seems very important to include this level of detail in the Machinery Regulation to allow the transfer of standards that have an Annex ZZ and ZA from the MD to the Machinery Regulation.

(Answered by the European Commission)

Such level of detail is normally not provided in a correlation table, because it is not intended as an equivalency table. Instead, the Machinery Regulation vs. Machinery Directive equivalency table may be established outside of the regulation. It can then be implemented by the standardisation organisation on the level of each harmonised standards that is developed or amended with a new Annex Z for the Machinery Regulation. Note that the numbering of the Essential Health and Safety Requirements between old Annex I and new Annex III are in most cases the same, in terms of topics, except for the newly added requirements.

Will the Standardisation Request be sent to ETSI as well? Or will it be sent only to CEN/CENELEC?

(Answered by the European Commission)

No decision has been taken yet.

The EC has made clear that Normative References to non-EN/ISO/IEC in harmonised standards to be published in the OJEU is no longer allowed. From your perspective, how will the TCs deal with this? Also, do you think this could slow down the development of standards?

(Answered by UNE – Spanish Standardisation Organisation)

There are already several examples of agreements between standardisation bodies and specific sectors that also generate standards, such as ISO ASTM standards. It is therefore the responsibility of the TCs to request the establishment of these specific agreements to develop more universal standards. In my opinion this would improve the speed of standards development.

Do you agree that one specific category of harmonised standards needs extra attention and priority during the review phase of the HAS consultants: those standards that deliver conformity with the Annex IA/B machinery. At least the published RFU's should be considered and incorporated in these standards.

(Answered by UNE – Spanish Standardisation Organisation)

In my opinion, the standards that grant conformity to the machines in annex A should be a priority, and of course the RFU's should be used as very useful information for the writing of the sections related to the use of the machines.

How shall we handle new ESHR that are not technically possible to comply with for certain products? In particular ESHR 3.5.4 Risk of contact with live overhead power lines is technically not possible to comply with for mobile cranes.

(Answered by UNE – Spanish Standardisation Organisation)

In my opinion, zero risk does not exist, so the measures proposed by the sector and that will be included in the standards must be evaluated by the HAS consultants, who must in turn provide technical guidelines for compliance with the requirements or evaluate the adequacy of the measures to reduce this risk. Currently, these requirements are intended to be addressed in type-C standards.

Questions related to Market Surveillance

Do you think that the obligations of the Fulfilment Service Provider are defined clearly enough for the purposes of the new Machinery Regulation, especially if we take into account the case where there is no other economic operator in the territory of the community. A comparison shows that the requirements from Art. 4 of the Market Surveillance Regulation 2019/1020 are insufficient to cover all the requirements that should be met by traditional economic operators?

This question does not arise due to the provisions in Article 4(1) of the Market Surveillance Regulation 2019/1020. Firstly, the provisions of this article apply without prejudice to any provisions from the EU Machinery Regulation. Then, Article 4(2) contains the obligation to designate an economic operator established in the EU if the manufacturer is not established in the EU. Article 4(3) sets out the obligations to cooperate with the market surveillance authority.

(Supplementary answer by the Market Surveillance Authorities)

Regulation 2019/1020 applies for the products subject to the machinery directive so also for the products subject to the new Machinery Regulation.

A fulfilment service provider is not a traditional economic operator so not all obligations can be applied even if there is no other economic operator within the Union (this is also the case for all other harmonisation legislations). Regulation 2019/1020 considers fulfilment service providers as another category of economic operators, but the new Machinery Regulation doesn't include any specific provisions/obligations for them. That doesn't mean they don't have any obligations. According to point 3.5 of the Blue Guide, art. 7 (obligation of cooperation) and 14 (powers of market surveillance authorities) of Regulation 2019/1020 are applicable to fulfilment service providers.

How can market surveillance authorities support and assist the industry to further overcome the current higher complexity and prevent or eliminate the manipulation or illegal practices in the EU market?

The task of market surveillance is to identify non-compliant products on the market and to take measures against these products. Therefore, assistance for the application of the new regulation is more likely to be obtained from trade associations, which provide information to their respective members.

What is the intention behind safeguard procedures?

(Answered by the Market Surveillance Authorities)

This is the market surveillance authority's action against non-compliant products.

When an economic operator doesn't want (or is not able, because of a bankruptcy) to take corrective measures, the market surveillance authority is obliged to step in. A market surveillance authority is only competent for its own country/territory. The safeguard procedure first consults all other market surveillance authorities (do they agree with the risk and the imposed measure) and afterwards obliges them to take the same measures in their country. This is to ensure a uniform approach throughout the whole Union.